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(54) **IMPRESSION PROCEDURE**

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CPC ***H04R 25/652*** (2013.01); ***H04R 25/658*** (2013.01); *H04R 2225/77* (2013.01)

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CPC H04R 2225/77; H04R 25/658; H04R 25/606; H04R 25/652; A61C 13/0004; A61C 9/004
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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,763,334	A	9/1956	Starkey
3,209,082	A	9/1965	McCarrell et al.
3,229,049	A	1/1966	Goldberg
3,440,314	A	4/1969	Eldon
3,449,768	A	6/1969	Doyle et al.
3,526,949	A	9/1970	Frank
3,549,818	A	12/1970	Justin

(Continued)

FOREIGN PATENT DOCUMENTS

AU	2004301961	A1	2/2005
CA	2242545	C	9/2009

(Continued)

OTHER PUBLICATIONS

Notice of Allowance dated Jun. 3, 2021 for U.S. Appl. No. 16/405,716.

(Continued)

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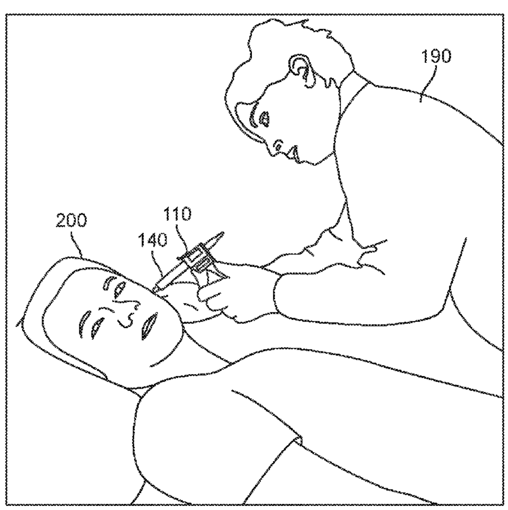
(57) **ABSTRACT**

Improved methods are described for the creation of impressions for use in the manufacture of hearing aid components. In addition methods for manufacturing components of hearing aid systems using improved ear canal impressions are described.

12 Claims, 6 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

3,585,416	A	6/1971	Mellen
3,594,514	A	7/1971	Wingrove
3,710,399	A	1/1973	Hurst
3,712,962	A	1/1973	Epley
3,764,748	A	10/1973	Branch et al.
3,808,179	A	4/1974	Gaylord
3,870,832	A	3/1975	Fredrickson
3,882,285	A	5/1975	Nunley et al.
3,965,430	A	6/1976	Brandt
3,985,977	A	10/1976	Beaty et al.
4,002,897	A	1/1977	Kleinman et al.
4,031,318	A	6/1977	Pitre
4,061,972	A	12/1977	Burgess
4,075,042	A	2/1978	Das
4,098,277	A	7/1978	Mendell
4,109,116	A	8/1978	Victoreen
4,120,570	A	10/1978	Gaylord
4,207,441	A	6/1980	Ricard et al.
4,248,899	A	2/1981	Lyon et al.
4,252,440	A	2/1981	Fedors et al.
4,281,419	A	8/1981	Treace
4,303,772	A	12/1981	Novicky
4,319,359	A	3/1982	Wolf
4,334,315	A	6/1982	Ono et al.
4,334,321	A	6/1982	Edelman
4,338,929	A	7/1982	Lundin et al.
4,339,954	A	7/1982	Anson et al.
4,357,497	A	11/1982	Hochmair et al.
4,375,016	A	2/1983	Harada
4,380,689	A	4/1983	Giannetti
4,428,377	A	1/1984	Zollner et al.
4,524,294	A	6/1985	Brody
4,540,761	A	9/1985	Kawamura et al.
4,556,122	A	12/1985	Goode
4,592,087	A	5/1986	Killion
4,606,329	A	8/1986	Hough
4,611,598	A	9/1986	Hortmann et al.
4,628,907	A	12/1986	Epley
4,641,377	A	2/1987	Rush et al.
4,652,414	A	3/1987	Schlaegel
4,654,554	A	3/1987	Kishi
4,689,819	A	8/1987	Killion
4,696,287	A	9/1987	Hortmann et al.
4,729,366	A	3/1988	Schaefer
4,741,339	A	5/1988	Harrison et al.
4,742,499	A	5/1988	Butler
4,756,312	A	7/1988	Epley
4,759,070	A	7/1988	Voroba et al.
4,766,607	A	8/1988	Feldman
4,774,933	A	10/1988	Hough et al.
4,776,322	A	10/1988	Hough et al.
4,782,818	A	11/1988	Mori
4,800,884	A	1/1989	Heide et al.
4,800,982	A	1/1989	Carlson
4,817,607	A	4/1989	Tatge
4,840,178	A	6/1989	Heide et al.
4,845,755	A	7/1989	Busch et al.
4,865,035	A	9/1989	Mori
4,870,688	A	9/1989	Voroba et al.
4,918,745	A	4/1990	Hutchison
4,932,405	A	6/1990	Peeters et al.
4,936,305	A	6/1990	Ashtiani et al.
4,944,301	A	7/1990	Widin et al.
4,948,855	A	8/1990	Novicky
4,957,478	A	9/1990	Maniglia et al.
4,963,963	A	10/1990	Dorman
4,982,434	A	1/1991	Lenhardt et al.
4,999,819	A	3/1991	Newnham et al.
5,003,608	A	3/1991	Carlson
5,012,520	A	4/1991	Steeger
5,015,224	A	5/1991	Maniglia
5,015,225	A	5/1991	Hough et al.
5,031,219	A	7/1991	Ward et al.
5,061,282	A	10/1991	Jacobs
5,066,091	A	11/1991	Stoy et al.
5,068,902	A	11/1991	Ward
5,094,108	A	3/1992	Kim et al.
5,117,461	A	5/1992	Moseley
5,142,186	A	8/1992	Cross et al.
5,163,957	A	11/1992	Sade et al.
5,167,235	A	12/1992	Seacord et al.
5,201,007	A	4/1993	Ward et al.
5,220,612	A	6/1993	Tibbetts et al.
5,259,032	A	11/1993	Perkins et al.
5,272,757	A	12/1993	Scofield et al.
5,276,910	A	1/1994	Buchele
5,277,694	A	1/1994	Leysieffer et al.
5,282,858	A	2/1994	Bisch et al.
5,296,797	A	3/1994	Bartlett
5,298,692	A	3/1994	Ikeda et al.
5,338,287	A	8/1994	Miller et al.
5,360,388	A	11/1994	Spindel et al.
5,378,933	A	1/1995	Pfannenmueller et al.
5,402,496	A	3/1995	Soli et al.
5,411,467	A	5/1995	Hortmann et al.
5,424,698	A	6/1995	Dydyk et al.
5,425,104	A	6/1995	Shennib
5,440,082	A	8/1995	Claes
5,440,237	A	8/1995	Brown et al.
5,455,994	A	10/1995	Termeer et al.
5,456,654	A	10/1995	Ball
5,531,787	A	7/1996	Lesinski et al.
5,531,954	A	7/1996	Heide et al.
5,535,282	A	7/1996	Luca
5,554,096	A	9/1996	Ball
5,558,618	A	9/1996	Maniglia
5,571,148	A	11/1996	Loeb et al.
5,572,594	A	11/1996	Devoe et al.
5,606,621	A	2/1997	Reiter et al.
5,624,376	A	4/1997	Ball et al.
5,654,530	A	8/1997	Sauer et al.
5,692,059	A	11/1997	Kruger
5,699,809	A	12/1997	Combs et al.
5,701,348	A	12/1997	Shennib et al.
5,707,338	A	1/1998	Adams et al.
5,715,321	A	2/1998	Andrea et al.
5,721,783	A	2/1998	Anderson
5,722,411	A	3/1998	Suzuki et al.
5,729,077	A	3/1998	Newnham et al.
5,740,258	A	4/1998	Goodwin-Johansson
5,742,692	A	4/1998	Garcia et al.
5,749,912	A	5/1998	Zhang et al.
5,762,583	A	6/1998	Adams et al.
5,772,575	A	6/1998	Lesinski et al.
5,774,259	A	6/1998	Saitoh et al.
5,782,744	A	7/1998	Money
5,788,711	A	8/1998	Lehner et al.
5,795,287	A	8/1998	Ball et al.
5,797,834	A	8/1998	Goode
5,800,336	A	9/1998	Ball et al.
5,804,109	A	9/1998	Perkins
5,804,907	A	9/1998	Park et al.
5,814,095	A	9/1998	Mueller et al.
5,824,022	A	10/1998	Zilberman et al.
5,825,122	A	10/1998	Givargizov et al.
5,836,863	A	11/1998	Bushek et al.
5,842,967	A	12/1998	Kroll
5,851,199	A	12/1998	Peerless et al.
5,857,958	A	1/1999	Ball et al.
5,859,916	A	1/1999	Ball et al.
5,868,682	A	2/1999	Combs et al.
5,879,283	A	3/1999	Adams et al.
5,888,187	A	3/1999	Jaeger et al.
5,897,486	A	4/1999	Ball et al.
5,899,847	A	5/1999	Adams et al.
5,900,274	A	5/1999	Chatterjee et al.
5,906,635	A	5/1999	Maniglia
5,913,815	A	6/1999	Ball et al.
5,922,017	A	7/1999	Bredberg et al.
5,922,077	A	7/1999	Espy et al.
5,935,170	A	8/1999	Haakansson et al.
5,940,519	A	8/1999	Kuo
5,949,895	A	9/1999	Ball et al.
5,951,601	A	9/1999	Lesinski et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,984,859	A	11/1999	Lesinski
5,987,146	A	11/1999	Pluvinage et al.
6,001,129	A	12/1999	Bushek et al.
6,005,955	A	12/1999	Kroll et al.
6,011,984	A	1/2000	Van Antwerp et al.
6,024,717	A	2/2000	Ball et al.
6,038,480	A	3/2000	Hrdlicka et al.
6,045,528	A	4/2000	Arenberg et al.
6,050,933	A	4/2000	Bushek et al.
6,067,474	A	5/2000	Schulman et al.
6,068,589	A	5/2000	Neukermans
6,068,590	A	5/2000	Brisken
6,072,884	A	6/2000	Kates
6,084,975	A	7/2000	Perkins
6,093,144	A	7/2000	Jaeger et al.
6,135,612	A	10/2000	Clore
6,137,889	A	10/2000	Shennib et al.
6,139,488	A	10/2000	Ball
6,153,966	A	11/2000	Neukermans
6,168,948	B1	1/2001	Anderson et al.
6,174,278	B1	1/2001	Jaeger et al.
6,175,637	B1	1/2001	Fujihira et al.
6,181,801	B1	1/2001	Puthuff et al.
6,190,305	B1	2/2001	Ball et al.
6,190,306	B1	2/2001	Kennedy
6,208,445	B1	3/2001	Reime
6,216,040	B1	4/2001	Harrison
6,217,508	B1	4/2001	Ball et al.
6,219,427	B1	4/2001	Kates et al.
6,222,302	B1	4/2001	Imada et al.
6,222,927	B1	4/2001	Feng et al.
6,240,192	B1	5/2001	Brennan et al.
6,241,767	B1	6/2001	Stennert et al.
6,259,951	B1	7/2001	Kuzma et al.
6,261,224	B1	7/2001	Adams et al.
6,264,603	B1	7/2001	Kennedy
6,277,148	B1	8/2001	Dormer
6,312,959	B1	11/2001	Datskos
6,339,648	B1	1/2002	McIntosh et al.
6,342,035	B1	1/2002	Kroll et al.
6,354,990	B1	3/2002	Juneau et al.
6,359,993	B2	3/2002	Brimhall
6,366,863	B1	4/2002	Bye et al.
6,374,143	B1	4/2002	Berrang et al.
6,385,363	B1	5/2002	Rajic et al.
6,387,039	B1	5/2002	Moses
6,390,971	B1	5/2002	Adams et al.
6,393,130	B1	5/2002	Stonikas et al.
6,422,991	B1	7/2002	Jaeger
6,432,248	B1	8/2002	Popp et al.
6,434,246	B1	8/2002	Kates et al.
6,434,247	B1	8/2002	Kates et al.
6,436,028	B1	8/2002	Dormer
6,438,244	B1	8/2002	Juneau et al.
6,445,799	B1	9/2002	Taenzer et al.
6,473,512	B1	10/2002	Juneau et al.
6,475,134	B1	11/2002	Ball et al.
6,491,622	B1	12/2002	Kasic, II et al.
6,491,644	B1	12/2002	Vujanic et al.
6,491,722	B1	12/2002	Kroll et al.
6,493,453	B1	12/2002	Glendon
6,493,454	B1	12/2002	Loi et al.
6,498,858	B2	12/2002	Kates
6,507,758	B1	1/2003	Greenberg et al.
6,519,376	B2	2/2003	Biagi et al.
6,523,985	B2	2/2003	Hamanaka et al.
6,536,530	B2	3/2003	Schultz et al.
6,537,200	B2	3/2003	Leysieffer et al.
6,547,715	B1	4/2003	Mueller et al.
6,549,633	B1	4/2003	Westermann
6,549,635	B1	4/2003	Gebert
6,554,761	B1	4/2003	Puria et al.
6,575,894	B2	6/2003	Leysieffer et al.
6,592,513	B1	7/2003	Kroll et al.
6,603,860	B1	8/2003	Taenzer et al.
6,620,110	B2	9/2003	Schmid
6,626,822	B1	9/2003	Jaeger et al.
6,629,922	B1	10/2003	Puria et al.
6,631,196	B1	10/2003	Taenzer et al.
6,643,378	B2	11/2003	Schumaier
6,663,575	B2	12/2003	Leysieffer
6,668,062	B1	12/2003	Luo et al.
6,676,592	B2	1/2004	Ball et al.
6,681,022	B1	1/2004	Puthuff et al.
6,695,943	B2	2/2004	Juneau et al.
6,697,674	B2	2/2004	Leysieffer
6,724,902	B1	4/2004	Shennib et al.
6,726,618	B2	4/2004	Miller
6,726,718	B1	4/2004	Carlyle et al.
6,727,789	B2	4/2004	Tibbetts et al.
6,728,024	B2	4/2004	Ribak
6,735,318	B2	5/2004	Cho
6,754,358	B1	6/2004	Boesen et al.
6,754,359	B1	6/2004	Svean et al.
6,754,537	B1	6/2004	Harrison et al.
6,785,394	B1	8/2004	Olsen et al.
6,792,114	B1	9/2004	Kates et al.
6,801,629	B2	10/2004	Brimhall et al.
6,829,363	B2	12/2004	Sacha
6,831,986	B2	12/2004	Kates
6,837,857	B2	1/2005	Stirnemann
6,842,647	B1	1/2005	Griffith et al.
6,888,949	B1	5/2005	Vanden et al.
6,900,926	B2	5/2005	Ribak
6,912,289	B2	6/2005	Vonlanthen et al.
6,920,340	B2	7/2005	Laderman
6,931,231	B1	8/2005	Griffin
6,940,988	B1	9/2005	Shennib et al.
6,940,989	B1	9/2005	Shennib et al.
6,942,989	B2	9/2005	Felkner et al.
D512,979	S	12/2005	Corcoran et al.
6,975,402	B2	12/2005	Bisson et al.
6,978,159	B2	12/2005	Feng et al.
7,020,297	B2	3/2006	Fang et al.
7,024,010	B2	4/2006	Saunders et al.
7,043,037	B2	5/2006	Lichtblau et al.
7,050,675	B2	5/2006	Zhou et al.
7,050,876	B1	5/2006	Fu et al.
7,057,256	B2	6/2006	Mazur et al.
7,058,182	B2	6/2006	Kates
7,058,188	B1	6/2006	Allred
7,072,475	B1	7/2006	Denap et al.
7,076,076	B2	7/2006	Bauman
7,095,981	B1	8/2006	Voroba et al.
7,167,572	B1	1/2007	Harrison et al.
7,174,026	B2	2/2007	Niederdrank et al.
7,179,238	B2	2/2007	Hissong
7,181,034	B2	2/2007	Armstrong
7,203,331	B2	4/2007	Boesen
7,239,069	B2	7/2007	Cho
7,245,732	B2	7/2007	Jorgensen et al.
7,255,457	B2	8/2007	Ducharme et al.
7,266,208	B2	9/2007	Charvin et al.
7,289,639	B2	10/2007	Abel et al.
7,313,245	B1	12/2007	Shennib
7,315,211	B1	1/2008	Lee et al.
7,322,930	B2	1/2008	Jaeger et al.
7,349,741	B2	3/2008	Maltan et al.
7,354,792	B2	4/2008	Mazur et al.
7,376,563	B2	5/2008	Leysieffer et al.
7,390,689	B2	6/2008	Mazur et al.
7,394,909	B1	7/2008	Widmer et al.
7,421,087	B2	9/2008	Perkins et al.
7,424,122	B2	9/2008	Ryan
7,444,877	B2	11/2008	Li et al.
7,547,275	B2	6/2009	Cho et al.
7,630,646	B2	12/2009	Anderson et al.
7,645,877	B2	1/2010	Gmeiner et al.
7,668,325	B2	2/2010	Puria et al.
7,747,295	B2	6/2010	Choi
7,778,434	B2	8/2010	Juneau et al.
7,809,150	B2	10/2010	Natarajan et al.
7,822,215	B2	10/2010	Carazo et al.
7,826,632	B2	11/2010	Von Buol et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,853,033	B2	12/2010	Maltan et al.
7,867,160	B2	1/2011	Pluvinage et al.
7,883,535	B2	2/2011	Cantin et al.
7,885,359	B2	2/2011	Meltzer
7,955,249	B2	6/2011	Perkins et al.
7,983,435	B2	7/2011	Moses
8,090,134	B2	1/2012	Takigawa et al.
8,099,169	B1	1/2012	Karunasiri
8,116,494	B2	2/2012	Rass
8,128,551	B2	3/2012	Jolly
8,157,730	B2	4/2012	LeBoeuf et al.
8,197,461	B1	6/2012	Arenberg et al.
8,204,786	B2	6/2012	LeBoeuf et al.
8,233,651	B1	7/2012	Haller
8,251,903	B2	8/2012	LeBoeuf et al.
8,284,970	B2	10/2012	Sacha
8,295,505	B2	10/2012	Weinans et al.
8,295,523	B2	10/2012	Fay et al.
8,320,601	B2	11/2012	Takigawa et al.
8,320,982	B2	11/2012	LeBoeuf et al.
8,340,310	B2	12/2012	Ambrose et al.
8,340,335	B1	12/2012	Shennib
8,391,527	B2	3/2013	Feucht et al.
8,396,235	B2	3/2013	Gebhardt et al.
8,396,239	B2	3/2013	Fay et al.
8,401,212	B2	3/2013	Puria et al.
8,401,214	B2	3/2013	Perkins et al.
8,506,473	B2	8/2013	Puria
8,512,242	B2	8/2013	LeBoeuf et al.
8,526,651	B2	9/2013	Lafort et al.
8,526,652	B2	9/2013	Ambrose et al.
8,526,971	B2	9/2013	Giniger et al.
8,545,383	B2	10/2013	Wenzel et al.
8,600,089	B2	12/2013	Wenzel et al.
8,647,270	B2	2/2014	LeBoeuf et al.
8,652,040	B2	2/2014	LeBoeuf et al.
8,684,922	B2	4/2014	Tran
8,696,054	B2	4/2014	Crum
8,696,541	B2	4/2014	Pluvinage et al.
8,700,111	B2	4/2014	LeBoeuf et al.
8,702,607	B2	4/2014	LeBoeuf et al.
8,715,152	B2	5/2014	Puria et al.
8,715,153	B2	5/2014	Puria et al.
8,715,154	B2	5/2014	Perkins et al.
8,761,423	B2	6/2014	Wagner et al.
8,787,609	B2	7/2014	Perkins et al.
8,788,002	B2	7/2014	LeBoeuf et al.
8,817,998	B2	8/2014	Inoue
8,824,715	B2	9/2014	Fay et al.
8,837,758	B2	9/2014	Knudsen
8,845,705	B2	9/2014	Perkins et al.
8,855,323	B2	10/2014	Kroman
8,858,419	B2	10/2014	Puria et al.
8,885,860	B2	11/2014	Djalilian et al.
8,886,269	B2	11/2014	LeBoeuf et al.
8,888,701	B2	11/2014	LeBoeuf et al.
8,923,941	B2	12/2014	LeBoeuf et al.
8,929,965	B2	1/2015	LeBoeuf et al.
8,929,966	B2	1/2015	LeBoeuf et al.
8,934,952	B2	1/2015	LeBoeuf et al.
8,942,776	B2	1/2015	LeBoeuf et al.
8,961,415	B2	2/2015	LeBoeuf et al.
8,986,187	B2	3/2015	Perkins et al.
8,989,830	B2	3/2015	LeBoeuf et al.
9,044,180	B2	6/2015	LeBoeuf et al.
9,049,528	B2	6/2015	Fay et al.
9,055,379	B2	6/2015	Puria et al.
9,131,312	B2	9/2015	LeBoeuf et al.
9,154,891	B2	10/2015	Puria et al.
9,211,069	B2	12/2015	Larsen et al.
9,226,083	B2	12/2015	Puria et al.
9,277,335	B2	3/2016	Perkins et al.
9,289,135	B2	3/2016	LeBoeuf et al.
9,289,175	B2	3/2016	LeBoeuf et al.
9,301,696	B2	4/2016	LeBoeuf et al.
9,314,167	B2	4/2016	LeBoeuf et al.
9,392,377	B2	7/2016	Olsen et al.
9,427,191	B2	8/2016	LeBoeuf
9,497,556	B2	11/2016	Kaltenbacher et al.
9,521,962	B2	12/2016	LeBoeuf
9,524,092	B2	12/2016	Ren et al.
9,538,921	B2	1/2017	LeBoeuf et al.
9,544,700	B2	1/2017	Puria et al.
9,564,862	B2	2/2017	Hoyerby
9,591,409	B2	3/2017	Puria et al.
9,749,758	B2	8/2017	Puria et al.
9,750,462	B2	9/2017	LeBoeuf et al.
9,788,785	B2	10/2017	LeBoeuf
9,788,794	B2	10/2017	LeBoeuf et al.
9,794,653	B2	10/2017	Aumer et al.
9,794,688	B2	10/2017	You
9,801,552	B2	10/2017	Romesburg
9,808,204	B2	11/2017	LeBoeuf et al.
9,924,276	B2	3/2018	Wenzel
9,930,458	B2	3/2018	Freed et al.
9,949,035	B2	4/2018	Rucker et al.
9,949,039	B2	4/2018	Perkins et al.
9,949,045	B2	4/2018	Kure et al.
9,961,454	B2	5/2018	Puria et al.
9,964,672	B2	5/2018	Phair et al.
10,003,888	B2	6/2018	Stephanou et al.
10,034,103	B2	7/2018	Puria et al.
10,143,592	B2	12/2018	Goldstein
10,154,352	B2	12/2018	Perkins et al.
10,178,483	B2	1/2019	Teran et al.
10,206,045	B2	2/2019	Kaltenbacher et al.
10,237,663	B2	3/2019	Puria et al.
10,284,964	B2	5/2019	Olsen et al.
10,286,215	B2	5/2019	Perkins et al.
10,292,601	B2	5/2019	Perkins et al.
10,306,381	B2	5/2019	Sandhu et al.
10,492,010	B2	11/2019	Rucker et al.
10,511,913	B2	12/2019	Puria et al.
10,516,946	B2	12/2019	Puria et al.
10,516,949	B2	12/2019	Puria et al.
10,516,950	B2	12/2019	Perkins et al.
10,516,951	B2	12/2019	Wenzel
10,531,206	B2	1/2020	Freed et al.
10,555,100	B2	2/2020	Perkins et al.
10,609,492	B2	3/2020	Olsen et al.
10,743,110	B2	8/2020	Puria et al.
10,779,094	B2	9/2020	Rucker et al.
10,863,286	B2	12/2020	Perkins et al.
11,057,714	B2	7/2021	Puria et al.
11,058,305	B2	7/2021	Perkins et al.
11,070,927	B2	7/2021	Rucker et al.
11,102,594	B2	8/2021	Shaquer et al.
11,153,697	B2	10/2021	Olsen et al.
11,166,114	B2	11/2021	Perkins et al.
11,212,626	B2	12/2021	Larkin et al.
11,252,516	B2	2/2022	Wenzel
11,259,129	B2	2/2022	Freed et al.
11,310,605	B2	4/2022	Puria et al.
11,317,224	B2	4/2022	Puria
11,337,012	B2	5/2022	Atamaniuk et al.
11,350,226	B2	5/2022	Sandhu et al.
2001/0003788	A1	6/2001	Ball et al.
2001/0007050	A1	7/2001	Adelman
2001/0024507	A1	9/2001	Boesen
2001/0027342	A1	10/2001	Dormer
2001/0029313	A1	10/2001	Kennedy
2001/0053871	A1	12/2001	Zilberman et al.
2002/0025055	A1	2/2002	Stonikas et al.
2002/0035309	A1	3/2002	Leysieffer
2002/0048374	A1	4/2002	Soli et al.
2002/0085728	A1	7/2002	Shennib et al.
2002/0086715	A1	7/2002	Sahagen
2002/0172350	A1	11/2002	Edwards et al.
2002/0183587	A1	12/2002	Dormer
2003/0021903	A1	1/2003	Shlenker et al.
2003/0055311	A1	3/2003	Neukermans et al.
2003/0064746	A1	4/2003	Rader et al.
2003/0081803	A1	5/2003	Petilli et al.
2003/0097178	A1	5/2003	Roberson et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2003/0125602 A1 7/2003 Sokolich et al.
2003/0142841 A1 7/2003 Wiegand
2003/0208099 A1 11/2003 Ball
2003/0208888 A1 11/2003 Fearing et al.
2004/0093040 A1 5/2004 Boylston et al.
2004/0121291 A1 6/2004 Knapp et al.
2004/0158157 A1 8/2004 Jensen et al.
2004/0165742 A1 8/2004 Shennib et al.
2004/0166495 A1 8/2004 Greinwald, Jr. et al.
2004/0167377 A1 8/2004 Schafer et al.
2004/0190734 A1 9/2004 Kates
2004/0202339 A1 10/2004 O'Brien, Jr. et al.
2004/0202340 A1 10/2004 Armstrong et al.
2004/0208333 A1 10/2004 Cheung et al.
2004/0234089 A1 11/2004 Rembrand et al.
2004/0234092 A1 11/2004 Wada et al.
2004/0236416 A1 11/2004 Falotico
2004/0240691 A1 12/2004 Grafenberg
2005/0018859 A1 1/2005 Buchholz
2005/0020873 A1 1/2005 Berrang et al.
2005/0036639 A1 2/2005 Bachler et al.
2005/0038498 A1 2/2005 Dubrow et al.
2005/0088435 A1 4/2005 Geng
2005/0101830 A1 5/2005 Easter et al.
2005/0111683 A1 5/2005 Chabries et al.
2005/0117765 A1 6/2005 Meyer et al.
2005/0190939 A1 9/2005 Fretz
2005/0196005 A1 9/2005 Shennib et al.
2005/0222823 A1* 10/2005 Brumback H04R 25/652 703/1
2005/0226446 A1 10/2005 Luo et al.
2005/0267549 A1 12/2005 Della et al.
2005/0271870 A1 12/2005 Jackson
2005/0288739 A1 12/2005 Hassler, Jr. et al.
2006/0058573 A1 3/2006 Neisz et al.
2006/0062420 A1 3/2006 Araki
2006/0074159 A1 4/2006 Lu et al.
2006/0075175 A1 4/2006 Jensen et al.
2006/0161227 A1 7/2006 Walsh, Jr. et al.
2006/0161255 A1 7/2006 Zarowski et al.
2006/0177079 A1 8/2006 Baekgaard et al.
2006/0177082 A1 8/2006 Solomito et al.
2006/0183965 A1 8/2006 Kasic, II et al.
2006/0231914 A1 10/2006 Carey, III et al.
2006/0233398 A1 10/2006 Husung
2006/0237126 A1 10/2006 Guffrey et al.
2006/0247735 A1 11/2006 Honert et al.
2006/0256989 A1 11/2006 Olsen et al.
2006/0278245 A1 12/2006 Gan
2007/0030990 A1 2/2007 Fischer
2007/0036377 A1 2/2007 Stirnemann
2007/0076913 A1 4/2007 Schanz
2007/0083078 A1 4/2007 Easter et al.
2007/0127748 A1 6/2007 Carlile et al.
2007/0127752 A1 6/2007 Armstrong
2007/0127766 A1 6/2007 Combest
2007/0135870 A1 6/2007 Shanks et al.
2007/0161848 A1 7/2007 Dalton et al.
2007/0191673 A1 8/2007 Ball et al.
2007/0201713 A1 8/2007 Fang et al.
2007/0206825 A1 9/2007 Thomasson
2007/0223755 A1 9/2007 Salvetti et al.
2007/0225776 A1 9/2007 Fritsch et al.
2007/0236704 A1 10/2007 Carr et al.
2007/0250119 A1 10/2007 Tyler et al.
2007/0251082 A1 11/2007 Milojevic et al.
2007/0258507 A1 11/2007 Lee et al.
2007/0286429 A1 12/2007 Grafenberg et al.
2008/0021518 A1 1/2008 Hochmair et al.
2008/0051623 A1 2/2008 Schneider et al.
2008/0054509 A1 3/2008 Berman et al.
2008/0063228 A1 3/2008 Mejia et al.
2008/0063231 A1 3/2008 Juneau et al.
2008/0077198 A1 3/2008 Webb et al.
2008/0089292 A1 4/2008 Kitazoe et al.
2008/0107292 A1 5/2008 Kornagel
2008/0123866 A1 5/2008 Rule et al.
2008/0130927 A1 6/2008 Theverapperuma et al.
2008/0188707 A1 8/2008 Bernard et al.
2008/0298600 A1 12/2008 Poe et al.
2008/0300703 A1 12/2008 Widmer et al.
2009/0016553 A1 1/2009 Ho et al.
2009/0023976 A1 1/2009 Cho et al.
2009/0043149 A1 2/2009 Abel et al.
2009/0076581 A1 3/2009 Gibson
2009/0131742 A1 5/2009 Cho et al.
2009/0141919 A1 6/2009 Spitaels et al.
2009/0149697 A1 6/2009 Steinhardt et al.
2009/0157143 A1 6/2009 Edler et al.
2009/0175474 A1 7/2009 Salvetti et al.
2009/0246627 A1 10/2009 Park
2009/0253951 A1 10/2009 Ball et al.
2009/0262966 A1 10/2009 Vestergaard et al.
2009/0281367 A1 11/2009 Cho et al.
2009/0310805 A1 12/2009 Petroff
2009/0316922 A1 12/2009 Merks et al.
2010/0036488 A1 2/2010 De Juan, Jr. et al.
2010/0085176 A1 4/2010 Flick
2010/0103404 A1 4/2010 Remke et al.
2010/0114190 A1 5/2010 Bendett et al.
2010/0145135 A1 6/2010 Ball et al.
2010/0171369 A1 7/2010 Baarman et al.
2010/0172507 A1 7/2010 Merks
2010/0177918 A1 7/2010 Keady et al.
2010/0222639 A1 9/2010 Purcell et al.
2010/0260364 A1 10/2010 Merks
2010/0272299 A1 10/2010 Van Schuylenbergh et al.
2010/0290653 A1 11/2010 Wiggins et al.
2010/0322452 A1 12/2010 Ladabaum et al.
2011/0062793 A1 3/2011 Azancot et al.
2011/0069852 A1 3/2011 Arndt et al.
2011/0084654 A1 4/2011 Julstrom et al.
2011/0112462 A1 5/2011 Parker et al.
2011/0116666 A1 5/2011 Dittberner et al.
2011/0125222 A1 5/2011 Perkins et al.
2011/0130622 A1 6/2011 Ilberg et al.
2011/0144414 A1 6/2011 Spearman et al.
2011/0164771 A1 7/2011 Jensen et al.
2011/0196460 A1 8/2011 Weiss
2011/0221391 A1 9/2011 Won et al.
2011/0249845 A1 10/2011 Kates
2011/0249847 A1 10/2011 Salvetti et al.
2011/0257290 A1* 10/2011 Zeller A61K 6/90 523/109
2011/0258839 A1 10/2011 Probst
2011/0271965 A1 11/2011 Parkins et al.
2012/0008807 A1 1/2012 Gran
2012/0038881 A1 2/2012 Amirparviz et al.
2012/0039493 A1 2/2012 Rucker et al.
2012/0092461 A1* 4/2012 Fisker H04N 13/296 348/46
2012/0114157 A1 5/2012 Arndt et al.
2012/0140967 A1 6/2012 Aubert et al.
2012/0217087 A1 8/2012 Ambrose et al.
2012/0236524 A1 9/2012 Pugh et al.
2012/0263339 A1 10/2012 Funahashi
2013/0004004 A1 1/2013 Zhao et al.
2013/0034258 A1 2/2013 Lin
2013/0083938 A1 4/2013 Bakalos et al.
2013/0089227 A1 4/2013 Kates
2013/0195300 A1 8/2013 Larsen et al.
2013/0230204 A1 9/2013 Monahan et al.
2013/0303835 A1 11/2013 Koskowich
2013/0308782 A1 11/2013 Dittberner et al.
2013/0308807 A1 11/2013 Burns
2013/0343584 A1 12/2013 Bennett et al.
2013/0343585 A1 12/2013 Bennett et al.
2013/0343587 A1 12/2013 Naylor et al.
2014/0084698 A1 3/2014 Asanuma et al.
2014/0107423 A1 4/2014 Yaacobi
2014/0153761 A1 6/2014 Shennib et al.
2014/0169603 A1 6/2014 Sacha et al.
2014/0177863 A1 6/2014 Parkins
2014/0194891 A1 7/2014 Shahoian

(56) **References Cited**

U.S. PATENT DOCUMENTS

2014/0254856	A1	9/2014	Blick et al.
2014/0286514	A1	9/2014	Pluvinage et al.
2014/0288356	A1	9/2014	Van Vlem
2014/0288358	A1	9/2014	Puria et al.
2014/0296620	A1	10/2014	Puria et al.
2014/0321657	A1	10/2014	Stirnemann
2014/0379874	A1	12/2014	Starr et al.
2015/0021568	A1	1/2015	Gong et al.
2015/0049889	A1	2/2015	Bern
2015/0117689	A1	4/2015	Bergs et al.
2015/0124985	A1	5/2015	Kim et al.
2015/0201269	A1	7/2015	Dahl
2015/0222978	A1	8/2015	Murozaki
2015/0245131	A1	8/2015	Facteau et al.
2015/0358743	A1	12/2015	Killion
2016/0008176	A1	1/2016	Goldstein
2016/0064814	A1	3/2016	Jang et al.
2016/0087687	A1	3/2016	Kesler et al.
2016/0094043	A1	3/2016	Hao et al.
2016/0277854	A1	9/2016	Puria et al.
2016/0309265	A1	10/2016	Pluvinage et al.
2016/0309266	A1	10/2016	Olsen et al.
2016/0330555	A1	11/2016	Vonlanthen et al.
2017/0040012	A1	2/2017	Goldstein
2017/0095202	A1	4/2017	Facteau et al.
2017/0180888	A1	6/2017	Andersson et al.
2017/0195806	A1	7/2017	Atamaniuk et al.
2017/0257710	A1	9/2017	Parker
2018/0077503	A1	3/2018	Shaquer et al.
2018/0077504	A1	3/2018	Shaquer et al.
2018/0213331	A1	7/2018	Rucker et al.
2018/0262846	A1	9/2018	Perkins et al.
2018/0317026	A1	11/2018	Puria
2018/0376255	A1	12/2018	Parker
2019/0166438	A1	5/2019	Perkins et al.
2019/0253811	A1	8/2019	Unno et al.
2019/0253815	A1	8/2019	Atamaniuk et al.
2020/0037082	A1	1/2020	Perkins et al.
2020/0128338	A1	4/2020	Shaquer et al.
2020/0186942	A1	6/2020	Flaherty et al.
2020/0336843	A1	10/2020	Lee et al.
2020/0396551	A1	12/2020	Dy et al.
2021/0029451	A1	1/2021	Fitz et al.
2021/0186343	A1	6/2021	Perkins et al.
2021/0266686	A1	8/2021	Puria et al.
2021/0274293	A1	9/2021	Perkins et al.
2021/0306777	A1	9/2021	Rucker et al.
2021/0314712	A1	10/2021	Shaquer et al.
2021/0392449	A1	12/2021	Flaherty et al.
2022/0007114	A1	1/2022	Perkins et al.
2022/0007115	A1	1/2022	Perkins et al.
2022/0007118	A1	1/2022	Rucker et al.
2022/0007120	A1	1/2022	Olsen et al.
2022/0046366	A1	2/2022	Larkin et al.
2022/0086572	A1	3/2022	Flaherty et al.
2022/0150650	A1	5/2022	Rucker

FOREIGN PATENT DOCUMENTS

CN	1176731	A	3/1998
CN	101459868	A	6/2009
CN	101489171	A	7/2009
CN	102301747	A	12/2011
CN	105491496	A	4/2016
DE	2044870	A1	3/1972
DE	3243850	A1	5/1984
DE	3508830	A1	9/1986
DE	102013114771	A1	6/2015
EP	0092822	A2	11/1983
EP	0242038	A2	10/1987
EP	0291325	A2	11/1988
EP	0296092	A2	12/1988
EP	0242038	A3	5/1989
EP	0296092	A3	8/1989
EP	0352954	A2	1/1990
EP	0291325	A3	6/1990
EP	0352954	A3	8/1991
EP	1035753	A1	9/2000
EP	1435757	A1	7/2004
EP	1845919	A1	10/2007
EP	1955407	A1	8/2008
EP	1845919	B1	9/2010
EP	2272520	A1	1/2011
EP	2301262	A1	3/2011
EP	2752030	A1	7/2014
EP	3101519	A1	12/2016
EP	2425502	B1	1/2017
EP	2907294	B1	5/2017
EP	3183814	A1	6/2017
EP	3094067	B1	10/2017
EP	3006079	B1	3/2019
FR	2455820	A1	11/1980
GB	2085694	A	4/1982
JP	S60154800	A	8/1985
JP	S621726	B2	1/1987
JP	S6443252	A	2/1989
JP	H09327098	A	12/1997
JP	2000504913	A	4/2000
JP	2004187953	A	7/2004
JP	2004193908	A	7/2004
JP	2005516505	A	6/2005
JP	2006060833	A	3/2006
KR	100624445	B1	9/2006
WO	WO-9209181	A1	5/1992
WO	WO-9501678	A1	1/1995
WO	WO-9621334	A1	7/1996
WO	WO-9736457	A1	10/1997
WO	WO-9745074	A1	12/1997
WO	WO-9806236	A1	2/1998
WO	WO-9903146	A1	1/1999
WO	WO-9915111	A1	4/1999
WO	WO-0022875	A2	4/2000
WO	WO-0022875	A3	7/2000
WO	WO-0150815	A1	7/2001
WO	WO-0158206	A2	8/2001
WO	WO-0176059	A2	10/2001
WO	WO-0158206	A3	2/2002
WO	WO-0239874	A2	5/2002
WO	WO-0239874	A3	2/2003
WO	WO-03030772	A2	4/2003
WO	WO-03063542	A2	7/2003
WO	WO-03063542	A3	1/2004
WO	WO-2004010733	A1	1/2004
WO	WO-2005015952	A1	2/2005
WO	WO-2005107320	A1	11/2005
WO	WO-2006014915	A2	2/2006
WO	WO-2006037156	A1	4/2006
WO	WO-2006039146	A2	4/2006
WO	WO-2006042298	A2	4/2006
WO	WO-2006071210	A1	7/2006
WO	WO-2006075169	A1	7/2006
WO	WO-2006075175	A1	7/2006
WO	WO-2006118819	A2	11/2006
WO	WO-2006042298	A3	12/2006
WO	WO-2007023164	A1	3/2007
WO	WO-2009046329	A1	4/2009
WO	WO-2009047370	A2	4/2009
WO	WO-2009049320	A1	4/2009
WO	WO-2009056167	A1	5/2009
WO	WO-2009062142	A1	5/2009
WO	WO-2009047370	A3	7/2009
WO	WO-2009125903	A1	10/2009
WO	WO-2009145842	A2	12/2009
WO	WO-2009146151	A2	12/2009
WO	WO-2009155358	A1	12/2009
WO	WO-2009155361	A1	12/2009
WO	WO-2009155385	A1	12/2009
WO	WO-2010033932	A1	3/2010
WO	WO-2010033933	A1	3/2010
WO	WO-2010077781	A2	7/2010
WO	WO-2010147935	A1	12/2010
WO	WO-2010148345	A2	12/2010
WO	WO-2011005500	A2	1/2011
WO	WO-2012088187	A2	6/2012

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO-2012149970 A1	11/2012
WO	WO-2013016336 A2	1/2013
WO	WO-2016011044 A1	1/2016
WO	WO-2016045709 A1	3/2016
WO	WO-2016146487 A1	9/2016
WO	WO-2017045700 A1	3/2017
WO	WO-2017059218 A1	4/2017
WO	WO-2017059240 A1	4/2017
WO	WO-2017116791 A1	7/2017
WO	WO-2017116865 A1	7/2017
WO	WO-2018048794 A1	3/2018
WO	WO-2018081121 A1	5/2018
WO	WO-2018093733 A1	5/2018
WO	WO-2019055308 A1	3/2019
WO	WO-2019173470 A1	9/2019
WO	WO-2019199680 A1	10/2019
WO	WO-2019199683 A1	10/2019
WO	WO-2020176086 A1	9/2020
WO	WO-2021003087 A1	1/2021

OTHER PUBLICATIONS

Office action dated Nov. 27, 2020 for U.S. Appl. No. 16/405,716.

Asbeck, et al. Scaling Hard Vertical Surfaces with Compliant Microspine Arrays, The International Journal of Robotics Research 2006; 25; 1165-79.

Atasoy [Paper] Opto-acoustic Imaging, for BYM504E Biomedical Imaging Systems class at ITU, downloaded from the Internet www2.itu.edu.td—cilesiz/courses/BYM504-2005-OA504041413.pdf, 14 pages.

Athanassiou, et al. Laser controlled photomechanical actuation of photochromic polymers Microsystems. Rev. Adv. Mater. Sci. 2003; 5:245-251.

Autumn, et al. Dynamics of geckos running vertically, The Journal of Experimental Biology 209, 260-272, (2006).

Autumn, et al., Evidence for van der Waals adhesion in gecko setae, www.pnas.orgycgiydoiy10.1073ypnas.192252799 (2002).

Ayatollahi, et al. Design and Modeling of Micromachined Condenser MEMS Loudspeaker using Permanent Magnet Neodymium-Iron-Boron (Nd—Fe—B). IEEE International Conference on Semiconductor Electronics, 2006. ICSE '06, Oct. 29 2006-Dec. 1, 2006; 160-166.

Baer, et al. Effects of Low Pass Filtering on the Intelligibility of Speech in Noise for People With and Without Dead Regions at High Frequencies. J. Acost. Soc. Am 112 (3), pt. 1, (Sep. 2002), pp. 1133-1144.

Best, et al. The influence of high frequencies on speech localization. Abstract 981 (Feb. 24, 2003) from www.aro.org/abstracts/abstracts.html.

Birch, et al. Microengineered systems for the hearing impaired. IEE Colloquium on Medical Applications of Microengineering, Jan. 31, 1996; pp. 2/1-2/5.

Boedts. Tympanic epithelial migration, Clinical Otolaryngology 1978, 3, 249-253.

Burkhard, et al. Anthropometric Manikin for Acoustic Research. J. Acoust. Soc. Am., vol. 58, No. 1, (Jul. 1975), pp. 214-222.

Camacho-Lopez, et al. Fast Liquid Crystal Elastomer Swims Into the Dark, Electronic Liquid Crystal Communications. Nov. 26, 2003; 9 pages total.

Carlile, et al. Frequency bandwidth and multi-talker environments. Audio Engineering Society Convention 120. Audio Engineering Society, May 20-23, 2006. Paris, France. 118: 8 pages.

Carlile, et al. Spatialisation of talkers and the segregation of concurrent speech. Abstract 1264 (Feb. 24, 2004) from www.aro.org/abstracts/abstracts.html.

Cheng, et al. A Silicon Microspeaker for Hearing Instruments. Journal of Micromechanics and Microengineering 2004; 14(7):859-866.

Co-pending U.S. Appl. No. 17/356,217, inventors Imatani; Kyle et al., filed Jun. 23, 2021.

Dictionary.corn's (via American Heritage Medical Dictionary) online dictionary definition of 'percutaneous'. Accessed on Jun. 3, 2013. 2 pages.

Copy of Merriam-Webster's online dictionary definition of 'percutaneous'. Accessed on Jun. 3, 2013. 3 pages.

Datskos, et al. Photoinduced and thermal stress in silicon microcantilevers. Applied Physics Letters. Oct. 19, 1998; 73(16):2319-2321.

Decraemer, et al. A method for determining three-dimensional vibration in the ear. Hearing Res., 77:19-37 (1994).

Dundas et al. The Earlens Light-Driven Hearing Aid: Top 10 questions and answers. Hearing Review. 2018;25(2):36-39.

Ear. Downloaded from the Internet. Accessed Jun. 17, 2008. 4 pages. URL: http://wwwmgs.bionet.nsc.ru/mgs/gnw/trrd/thesaurus/Se/ear.html.

Edinger, J.R. High-Quality Audio Amplifier With Automatic Bias Control. Audio Engineering; Jun. 1947; pp. 7-9.

Fay. Cat eardrum mechanics. Ph.D. thesis. Dissertation submitted to Department of Aeronautics and Astronautics. Stanford University. May 2001; 210 pages total.

Fay, et al. Cat eardrum response mechanics. Mechanics and Computation Division. Department of Mechanical Engineering. Stanford University. 2002; 10 pages total.

Fay, et al. Preliminary evaluation of a light-based contact hearing device for the hearing impaired. Otol Neurotol. Jul. 2013;34(5):912-21. doi: 10.1097/MAO.0b013e31827de4b1.

Fay, et al. The discordant eardrum, PNAS, Dec. 26, 2006, vol. 103, No. 52, p. 19743-19748.

Fletcher. Effects of Distortion on the Individual Speech Sounds. Chapter 18, ASA Edition of Speech and Hearing in Communication, Acoust Soc.of Am. (republished in 1995) pp. 415-423.

Folkeard, et al. Detection, Speech Recognition, Loudness, and Preference Outcomes With a Direct Drive Hearing Aid: Effects of Bandwidth. Trends Hear. Jan.-Dec. 2021; 25: 1-17. doi: 10.1177/2331216521999139.

Freyman, et al. Spatial Release from Informational Masking in Speech Recognition. J. Acost. Soc. Am., vol. 109, No. 5, pt. 1, (May 2001); 2112-2122.

Freyman, et al. The Role of Perceived Spatial Separation in the Unmasking of Speech. J. Acoust. Soc. Am., vol. 106, No. 6, (Dec. 1999); 3578-3588.

Fritsch, et al. EarLens transducer behavior in high-field strength MRI scanners. Otolaryngol Head Neck Surg. Mar. 2009;140(3):426-8. doi: 10.1016/j.otohns.2008.10.016.

Galbraith et al. A wide-band efficient inductive transdermal power and data link with coupling insensitive gain IEEE Trans Biomed Eng. Apr. 1987;34(4):265-75.

Gantz, et al. Broad Spectrum Amplification with a Light Driven Hearing System. Combined Otolaryngology Spring Meetings, 2016 (Chicago).

Gantz, et al. Light Driven Hearing System: A Multi-Center Clinical Study. Association for Research in Otolaryngology Annual Meeting, 2016 (San Diego).

Gantz, et al. Light-Driven Contact Hearing Aid for Broad Spectrum Amplification: Safety and Effectiveness Pivotal Study. Otology & Neurotology Journal, 2016 (in review).

Gantz, et al. Light-Driven Contact Hearing Aid for Broad-Spectrum Amplification: Safety and Effectiveness Pivotal Study. Otology & Neurotology. Copyright 2016. 7 pages.

Ge, et al., Carbon nanotube-based synthetic gecko tapes, p. 10792-10795, PNAS, Jun. 26, 2007, vol. 104, No. 26.

Gennum. GA3280 Preliminary Data Sheet: Voyageur TD Open Platform DSP System for Ultra Low Power Audio Processing. Oct. 2006; 17 pages. Downloaded from the Internet: www.sounddesigntechnologies.com/products/pdf/37601DOC.pdf.

Gobin, et al. Comments on the physical basis of the active materials concept. Proc. SPIE 2003; 4512:84-92.

Gorb, et al. Structural Design and Biomechanics of Friction-Based Releasable Attachment Devices in Insects. Integr Comp Biol. Dec. 2002. 42(6):1127-1139. doi: 10.1093/icb/42.6.1127.

Hakansson, et al. Percutaneous vs. transcutaneous transducers for hearing by direct bone conduction (Abstract). Otolaryngol Head Neck Surg. Apr. 1990;102(4):339-44.

(56) **References Cited**

OTHER PUBLICATIONS

Hato, et al. Three-dimensional stapes footplate motion in human temporal bones. Audiol. Neurootol., 8:140-152 (Jan. 30, 2003).
Hofman, et al. Relearning Sound Localization With New Ears. Nature Neuroscience, vol. 1, No. 5, (Sep. 1998); 417-421.
International Search Report and Written Opinion dated Jan. 19, 2018 for International PCT Patent Application No. PCT/US2017/061388.
Izzo, et al. Laser Stimulation of Auditory Neurons: Effect of Shorter Pulse Duration and Penetration Depth. Biophys J. Apr. 15, 2008;94(8):3159-3166.
Izzo, et al. Laser Stimulation of the Auditory Nerve. Lasers Surg Med. Sep. 2006;38(8):745-753.
Izzo, et al. Selectivity of Neural Stimulation in the Auditory System: A Comparison of Optic and Electric Stimuli. J Biomed Opt. Mar.-Apr. 2007;12(2):021008.
Jackson, et al. Multiphoton and Transmission Electron Microscopy of Collagen in Ex Vivo Tympanic Membranes. Ninth Annual Symposium on Biomedical Computation at Stanford (BCATS). BCATS 2008 Abstract Book. Poster 18:56. Oct. 2008. URL: www.stanford.edu/~puria1/BCATS08.html.
Jian, et al. A 0.6 V, 1.66 mW energy harvester and audio driver for tympanic membrane transducer with wirelessly optical signal and power transfer. InCircuits and Systems (ISCAS), 2014 IEEE International Symposium on Jun. 1, 2014. 874-7. IEEE.
Jin, et al. Speech Localization. J. Audio Eng. Soc. convention paper, presented at the AES 112th Convention, Munich, Germany, May 10-13, 2002, 13 pages total.
Khaleghi, et al. Attenuating the ear canal feedback pressure of a laser-driven hearing aid. J Acoust Soc Am. Mar. 2017;141(3):1683.
Khaleghi, et al. Attenuating the feedback pressure of a light-activated hearing device to allows microphone placement at the ear canal entrance. IHCON 2016, International Hearing Aid Research Conference, Tahoe City, CA, Aug. 2016.
Khaleghi, et al. Characterization of Ear-Canal Feedback Pressure due to Umbo-Drive Forces: Finite-Element vs. Circuit Models. ARO Midwinter Meeting 2016, (San Diego).
Khaleghi, et al. Mechano-Electro-Magnetic Finite Element Model of a Balanced Armature Transducer for a Contact Hearing Aid. Proc. MoH 2017, Mechanics of Hearing workshop, Brock University, Jun. 2017.
Khaleghi, et al. Multiphysics Finite Element Model of a Balanced Armature Transducer used in a Contact Hearing Device. ARO 2017, 40th ARO MidWinter Meeting, Baltimore, MD, Feb. 2017.
Kiessling, et al. Occlusion Effect of Earmolds with Different Venting Systems. J Am Acad Audiol. Apr. 2005;16(4):237-49.
Killion, et al. The case of the missing dots: AI and SNR loss. The Hearing Journal, 1998. 51(5), 32-47.
Killion. Myths About Hearing in Noise and Directional Microphones. The Hearing Review. Feb. 2004; 11(2):14, 16, 18, 19, 72 & 73.
Killion. SNR loss: I can hear what people say but I can't understand them. The Hearing Review, 1997; 4(12):8-14.
Knight, D. Diode detectors for RF measurement. Paper. Jan. 1, 2016. [Retrieved from 1-16 online] (retrieved Feb. 11, 2020) abstract, p. 1; section 1, p. 6; section 1.3, p. 9; section 3 voltage-double rectifier, p. 21; section 5, p. 27. URL: g3ynh.info/circuits/Diode_det.pdf.
Lee, et al. A Novel Opto-Electromagnetic Actuator Coupled to the tympanic Membrane. J Biomech. Dec. 5, 2008;41(16):3515-8. Epub Nov. 7, 2008.
Lee, et al. The optimal magnetic force for a novel actuator coupled to the tympanic membrane: a finite element analysis. Biomedical engineering: applications, basis and communications. 2007; 19(3):171-177.
Levy, et al. Characterization of the available feedback gain margin at two device microphone locations, in the fossa triangularis and Behind the Ear, for the light-based contact hearing device. Acoustical Society of America (ASA) meeting, 2013 (San Francisco).
Levy, et al. Extended High-Frequency Bandwidth Improves Speech Reception in the Presence of Spatially Separated Masking Speech. Ear Hear. Sep.-Oct. 2015;36(5):e214-24. doi: 10.1097/AUD.0000000000000161.
Levy et al. Light-driven contact hearing aid: a removable direct-drive hearing device option for mild to severe sensorineural hearing impairment. Conference on Implantable Auditory Prostheses, Tahoe City, CA, Jul. 2017. 4 pages.
Lezal. Chalcogenide glasses—survey and progress. Journal of Optoelectronics and Advanced Materials. Mar. 2003; 5(1):23-34.
Mah. Fundamentals of photovoltaic materials. National Solar Power Research Institute. Dec. 21, 1998, 3-9.
Makino, et al. Epithelial migration in the healing process of tympanic membrane perforations. Eur Arch Otorhinolaryngol. 1990; 247: 352-355.
Makino, et al., Epithelial migration on the tympanic membrane and external canal, Arch Otorhinolaryngol (1986) 243:39-42.
Markoff. Intuition + Money: An Aha Moment. New York Times Oct. 11, 2008, p. BU4, 3 pages total.
Martin, et al. Utility of Monaural Spectral Cues is Enhanced in the Presence of Cues to Sound-Source Lateral Angle. JARO. 2004; 5:80-89.
McElveen et al. Overcoming High-Frequency Limitations of Air Conduction Hearing Devices Using a Light-Driven Contact Hearing Aid. Poster presentation at the Triological Society, 120th Annual Meeting at COSM, Apr. 28, 2017; San Diego, CA.
Michaels, et al., Auditory epithelial migration on the human tympanic membrane: II. The existence of two discrete migratory pathways and their embryologic correlates. Am J Anat. Nov. 1990. 189(3):189-200. DOI: 10.1002/aja.1001890302.
Moore, et al. Perceived naturalness of spectrally distorted speech and music. J Acoust Soc Am. Jul. 2003;114(1):408-19.
Moore, et al. Spectro-temporal characteristics of speech at high frequencies, and the potential for restoration of audibility to people with mild-to-moderate hearing loss. Ear Hear. Dec. 2008;29(6):907-22. doi: 10.1097/AUD.0b013e3181824616.
Moore. Loudness perception and intensity resolution. Cochlear Hearing Loss, Chapter 4, pp. 90-115, Whurr Publishers Ltd., London (1998).
Murphy, et al. Adhesion and anisotropic friction enhancements of angled heterogeneous micro-fiber arrays with spherical and spatula tips. Journal of Adhesion Science and Technology. vol. 21. No. 12-13. Aug. 2007. pp. 1281-1296. DOI: 10.1163/156856107782328380.
Murugasu, et al. Malleus-to-footplate versus malleus-to-stapes-head ossicular reconstruction prostheses: temporal bone pressure gain measurements and clinical audiological data. Otol Neurotol. Jul. 2005;26(4):572-82. DOI: 10.1097/01.mao.0000178151.44505.1b.
Musicant, et al. Direction-dependent spectral properties of cat external ear: new data and cross-species comparisons. J Acoust Soc Am. Feb. 1990. 87(2):757-781. DOI: 10.1121/1.399545.
National Semiconductor. LM4673 Boomer: Filterless, 2.65W, Mono, Class D Audio Power Amplifier. Nov. 1, 2007. 24 pages. [Data Sheet] downloaded from the Internet: URL: www.national.com/ds/LM/LM4673.pdf.
Nishihara, et al. Effect of changes in mass on middle ear function. Otolaryngol Head Neck Surg. Nov. 1993;109(5):889-910.
Notice of Allowance dated Oct. 5, 2021 for U.S. Appl. No. 16/405,716.
O'Connor, et al. Middle ear Cavity and Ear Canal Pressure-Driven Stapes Velocity Responses in Human Cadaveric Temporal Bones. J Acoust Soc Am. Sep. 2006;120(3):1517-28.
Park, et al. Design and analysis of a microelectromagnetic vibration transducer used as an implantable middle ear hearing aid. J. Micromech. Microeng. vol. 12 (2002), pp. 505-511.
Perkins, et al. Light-based Contact Hearing Device: Characterization of available Feedback Gain Margin at two device microphone locations. Presented at AAO-HNSF Annual Meeting, 2013 (Vancouver).
Perkins, et al. The EarLens Photonic Transducer: Extended bandwidth. Presented at AAO-HNSF Annual Meeting, 2011 (San Francisco).
Perkins, et al. The EarLens System: New sound transduction methods. Hear Res. Feb. 2, 2010; 10 pages total.

(56) **References Cited**

OTHER PUBLICATIONS

Perkins, R. Earlens tympanic contact transducer: a new method of sound transduction to the human ear. Otolaryngol Head Neck Surg. Jun. 1996;114(6):720-8.
Poosanaas, et al. Influence of sample thickness on the performance of photostrictive ceramics, J. App. Phys. Aug. 1, 1998; 84(3):1508-1512.
Puria et al. A gear in the middle ear. ARO Denver CO, 2007b.
Puria, et al. Cues above 4 kilohertz can improve spatially separated speech recognition. The Journal of the Acoustical Society of America, 2011, 129, 2384.
Puria, et al. Extending bandwidth above 4 kHz improves speech understanding in the presence of masking speech. Association for Research in Otolaryngology Annual Meeting, 2012 (San Diego).
Puria, et al. Extending bandwidth provides the brain what it needs to improve hearing in noise. First international conference on cognitive hearing science for communication, 2011 (Linkoping, Sweden).
Puria, et al. Hearing Restoration: Improved Multi-talker Speech Understanding. 5th International Symposium on Middle Ear Mechanics in Research and Otology (MEMRO), Jun. 2009 (Stanford University).
Puria, et al. Imaging, Physiology and Biomechanics of the middle ear: Towards understating the functional consequences of anatomy. Stanford Mechanics and Computation Symposium, 2005, ed Fong J.
Puria, et al. Malleus-to-footplate ossicular reconstruction prosthesis positioning: cochleovestibular pressure optimization. Otol Nerotol. May 2005; 26(3):368-379. DOI: 10.1097/01.mao.0000169788.07460.4a.
Puria, et al. Measurements and model of the cat middle ear: Evidence of tympanic membrane acoustic delay. J. Acoust. Soc. Am., 104(6):3463-3481 (Dec. 1998).
Puria, et al., Mechano-Acoustical Transformations in A. Basbaum et al., eds., The Senses: A Comprehensive Reference, v3, p. 165-201, Academic Press (2008).
Puria, et al. Middle Ear Morphometry From Cadaveric Temporal Bone MicroCT Imaging. Proceedings of the 4th International Symposium, Zurich, Switzerland, Jul. 27-30, 2006, Middle Ear Mechanics in Research and Otology, pp. 260-269.
Puria, et al. Sound-Pressure Measurements in the Cochlear Vestibule of Human-Cadaver Ears. Journal of the Acoustical Society of America. 1997; 101 (5-1): 2754-2770.
Puria, et al. Temporal-Bone Measurements of the Maximum Equivalent Pressure Output and Maximum Stable Gain of a Light-Driven Hearing System That Mechanically Stimulates the Umbo. Otol Neurotol. Feb. 2016;37(2):160-6. doi: 10.1097/MAO.0000000000000941.
Puria, et al. The EarLens Photonic Hearing Aid. Association for Research in Otolaryngology Annual Meeting, 2012 (San Diego).
Puria, et al. The Effects of bandwidth and microphone location on understanding of masked speech by normal-hearing and hearing-impaired listeners. International Conference for Hearing Aid Research (IHCON) meeting, 2012 (Tahoe City).
Puria, et al. Tympanic-membrane and malleus-incus-complex co-adaptations for high-frequency hearing in mammals. Hear Res. May 2010;263(1-2):183-90. doi: 10.1016/j.heares.2009.10.013. Epub Oct. 28, 2009.
Puria. Measurements of human middle ear forward and reverse acoustics: implications for otoacoustic emissions. J Acoust Soc Am. May 2003;113(5):2773-89.
Puria, S. Middle Ear Hearing Devices. Chapter 10. Part of the series Springer Handbook of Auditory Research pp. 273-308. Date: Feb. 9, 2013.
Qu, et al. Carbon nanotube arrays with strong shear binding-on and easy normal lifting-off. Science. Oct. 10, 2008. 322(5899):238-342. doi: 10.1126/science.1159503.
Robles, et al. Mechanics of the mammalian cochlea. Physiol Rev. Jul. 2001;81(3):1305-52.
Roush. SiOnyx Brings "Black Silicon" into the Light; Material Could Upend Solar, Imaging Industries. Xconomy, Oct. 12, 2008, retrieved from the Internet: www.xconomy.com/boston/2008/10/12/sionyx-brings-black-silicon-into-the-light¬material-could-upend-solar-imaging-industries 4 pages total.
Rubinstein. How cochlear implants encode speech. Curr Opin Otolaryngol Head Neck Surg. Oct. 2004. 12(5):444-448. DOI: 10.1097/01.moo.0000134452.24819.c0.
School of Physics Sydney, Australia. Acoustic Compliance, Inertance and Impedance. 1-6. (2018). http://www.animations.physics.unsw.edu.au/jw/compliance-inertance-impedance.htm.
Sekaric, et al. Nanomechanical resonant structures as tunable passive modulators. Applied Physics Letters. May 2002. 80(19):3617-3619. DOI: 10.1063/1.1479209.
Shaw. Transformation of Sound Pressure Level From the Free Field to the Eardrum in the Horizontal Plane. J. Acoust. Soc. Am., vol. 56, No. 6, (Dec. 1974), 1848-1861.
Shih, et al. Shape and displacement control of beams with various boundary conditions via photostrictive optical actuators. Proc. IMECE. Nov. 2003; 1-10.
Smith. The Scientist and Engineers Guide to Digital Signal Processing. California Technical Publishing. 1997. Chapter 22. pp. 351-372.
Song, et al. The development of a non-surgical direct drive hearing device with a wireless actuator coupled to the tympanic membrane. Applied Acoustics. Dec. 31, 2013;74(12):1511-8.
Sound Design Technologies. Voyager TD Open Platform DSP System for Ultra Low Power Audio Processing—GA3280 Data Sheet. Oct. 2007. 15 pages. Retrieved from the Internet: www.sounddes.com/pdf/37601DOC.pdf.
Spolenak, et al. Effects of contact shape on the scaling of biological attachments. Proc. R. Soc. A. 2005; 461:305-319.
Stenfelt, et al. Bone-Conducted Sound: Physiological and Clinical Aspects. Otology & Neurotology, Nov. 2005; 26 (6):1245-1261.
Struck, et al. Comparison of Real-world Bandwidth in Hearing Aids vs Earlens Light-driven Hearing Aid System. The Hearing Review. TechTopic: EarLens. Hearingreview.com. Mar. 14, 2017. pp. 24-28.
Stuchlik, et al. Micro-Nano Actuators Driven by Polarized Light. IEEE Proc. Sci. Meas. Techn. Mar. 2004; 151(2):131-136.
Suski, et al. Optically activated ZnO/SiG2/Si cantilever beams. Sensors and Actuators A: Physical. Sep. 1990. 24(3): 221-225. https://doi.org/10.1016/0924-4247(90)80062-A.
Takagi, et al. Mechanochemical Synthesis of Piezoelectric PLZT Powder. KONA. 2003; 51(21):234-241.
Thakoor, et al. Optical microactuation in piezoceramics. Proc. SPIE. Jul. 1998; 3328:376-391.
Thompson. Tutorial on microphone technologies for directional hearing aids. Hearing Journal. Nov. 2003; 56(11):14-16,18, 20-21.
Tzou, et al. Smart Materials, Precision Sensors/Actuators, Smart Structures, and Structronic Systems. Mechanics of Advanced Materials and Structures. 2004; 11:367-393.
Uchino, et al. Photostricitve actuators. Ferroelectrics. 2001; 258:147-158.
Vickers, et al. Effects of Low-Pass Filtering on the Intelligibility of Speech in Quiet for People With and Without Dead Regions at High Frequencies. J. Acoust. Soc. Am. Aug. 2001; 110(2):1164-1175.
Vinge. Wireless Energy Transfer by Resonant Inductive Coupling. Master of Science Thesis. Chalmers University of Technology. 1-83 (2015).
Vinikman-Pinhasi, et al. Piezoelectric and Piezooptic Effects in Porous Silicon. Applied Physics Letters, Mar. 2006; 88(11): 111905-1-111905-2. DOI: 10.1063/1.2186395.
Wang, et al. Preliminary Assessment of Remote Photoelectric Excitation of an Actuator for a Hearing Implant. Proceeding of the 2005 IEEE, Engineering in Medicine and Biology 27th Annual Conference, Shanghai, China. Sep. 1-4, 2005; 6233-6234.
Web Books Publishing, "The Ear," accessed online Jan. 22, 2013, available online Nov. 2, 2007 at http://www.web-books.com/eLibrary/Medicine/Physiology/Ear/Ear.htm.
Wiener, et al. On the Sound Pressure Transformation by the Head and Auditory Meatus of the Cat. Acta Otolaryngol. Mar. 1966; 61(3):255-269.

(56) **References Cited**

OTHER PUBLICATIONS

Wightman, et al. Monaural Sound Localization Revisited. J Acoust Soc Am. Feb. 1997;101(2):1050-1063.
Wiki. Sliding Bias Variant 1, Dynamic Hearing (2015).
Wikipedia. Headphones. Downloaded from the Internet. Accessed Oct. 27, 2008. 7 pages. URL: http://en.wikipedia.org/wiki/Headphones.
Wikipedia. Inductive Coupling. 1-2 (Jan. 11, 2018). https://en.wikipedia.org/wiki/Inductive_coupling.
Wikipedia. Pulse-density Coupling. 1-4 (Apr. 6, 2017). https://en.wikipedia.org/wiki/Pulse-density_modulation.
Wikipedia. Resonant Inductive Coupling. 1-11 (Jan. 12, 2018). https://en.wikipedia.org/wiki/Resonant_inductive_coupling#cite_note-13.
Yao, et al. Adhesion and sliding response of a biologically inspired fibrillar surface: experimental observations, J. R. Soc. Interface (2008) 5, 723-733 doi:10.1098/rsif.2007.1225 Published online Oct. 30, 2007.
Yao, et al. Maximum strength for intermolecular adhesion of nanospheres at an optimal size. J R Soc Interface. Nov. 6, 2008;5(28):1363-70. doi: 10.1098/rsif.2008.0066.
Yi, et al. Piezoelectric Microspeaker with Compressive Nitride Diaphragm. The Fifteenth IEEE International Conference on Micro Electro Mechanical Systems, 2002; 260-263.
Yu, et al. Photomechanics: Directed bending of a polymer film by light. Nature. Sep. 11, 2003;425(6954):145. DOI: 10.1038/425145a.

* cited by examiner

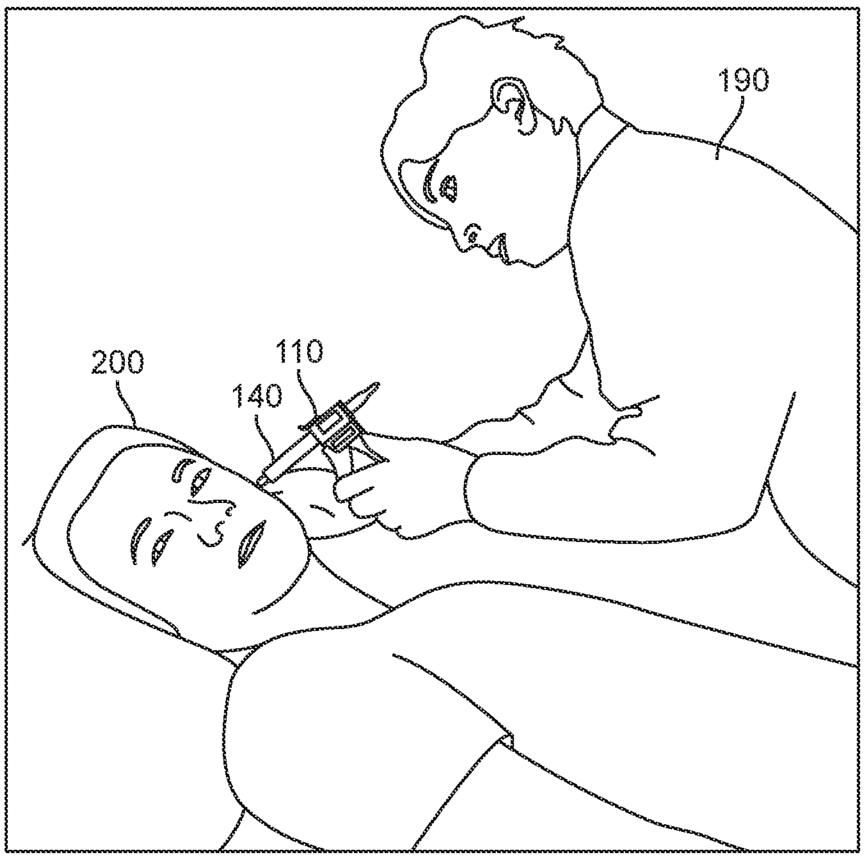


FIG. 1

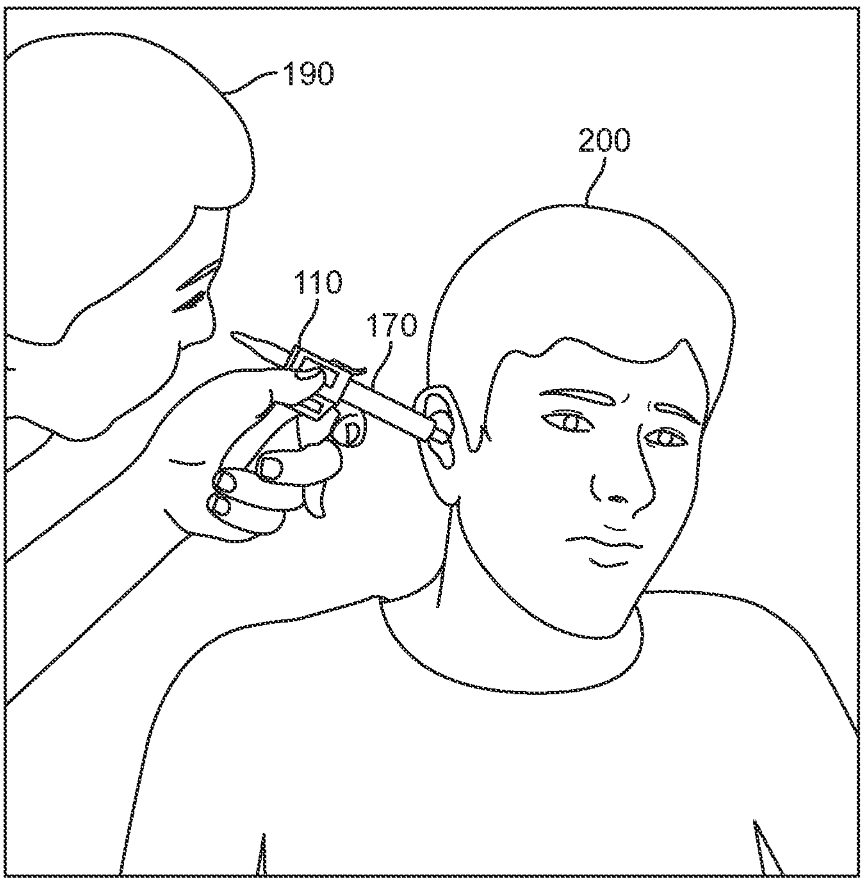


FIG. 2

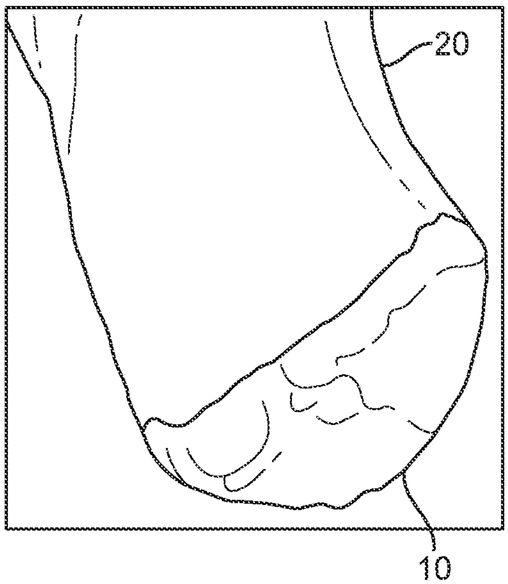


FIG. 3

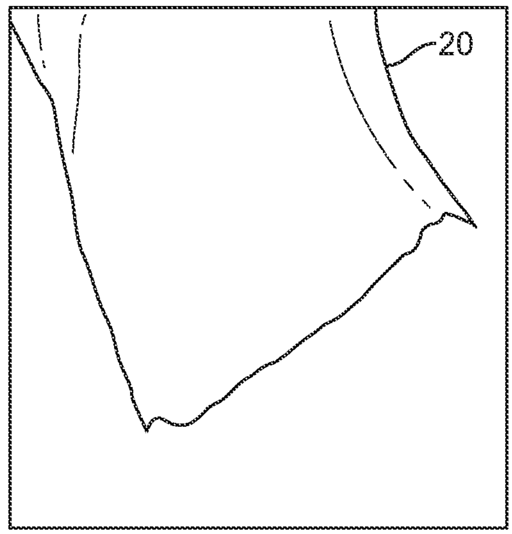


FIG. 4

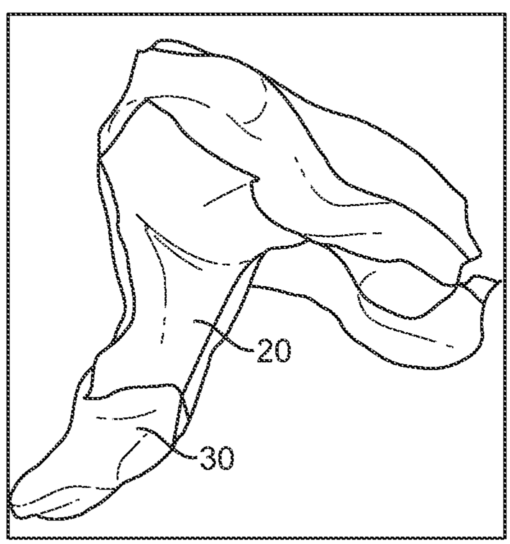


FIG. 5

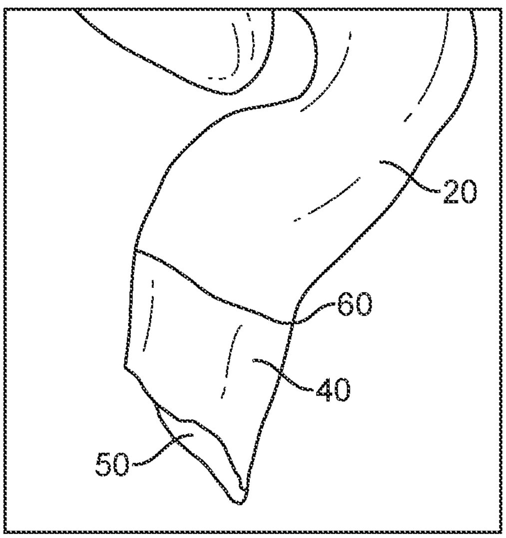


FIG. 6

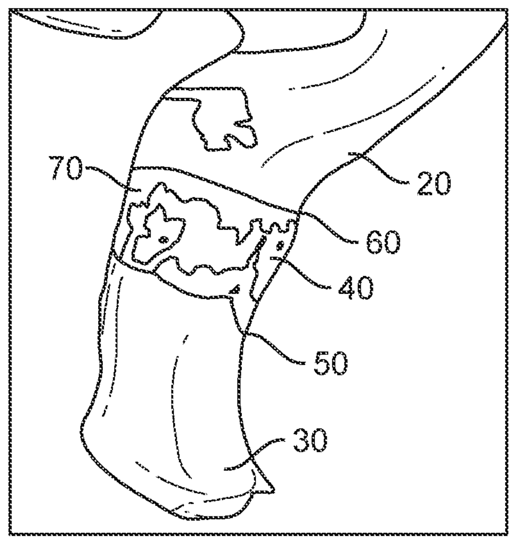


FIG. 7

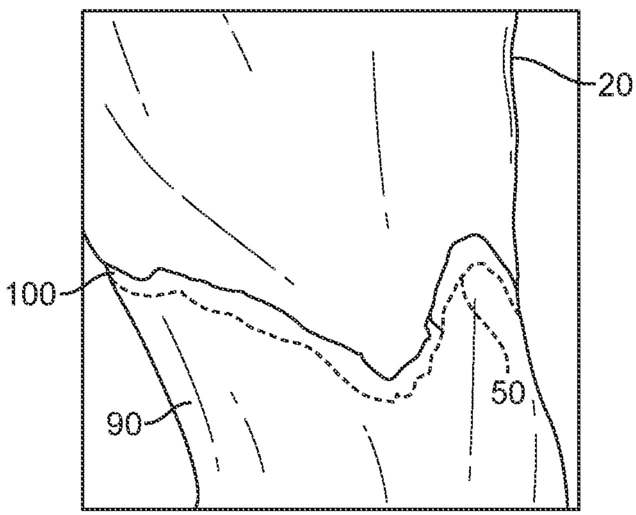


FIG. 8

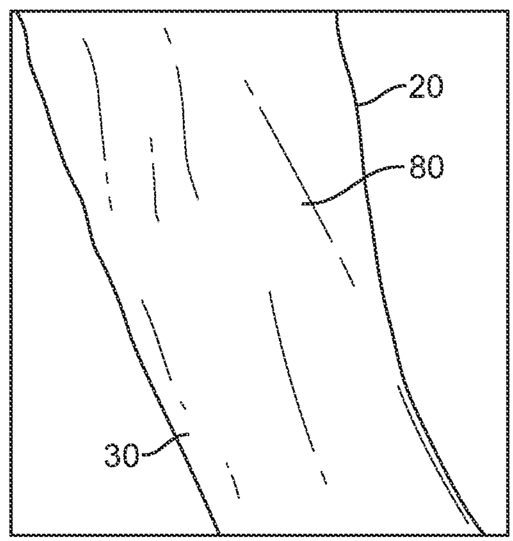


FIG. 9

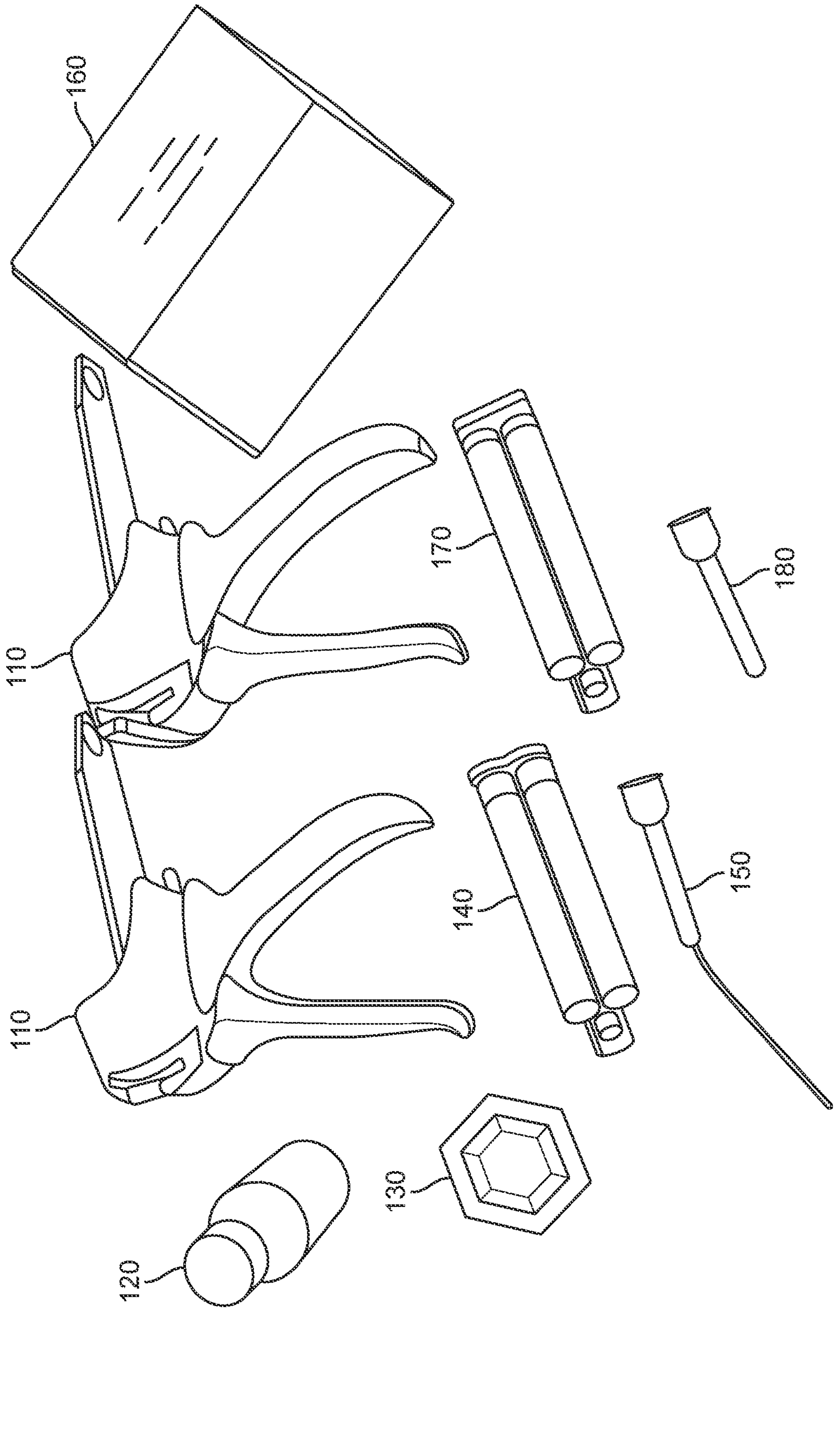


FIG. 10

IMPRESSION PROCEDURE

CROSS-REFERENCE

This application is a continuation of U.S. patent application Ser. No. 16/405,716, filed May 7, 2019, now U.S. Pat. No. 11,166,114; which is a continuation of PCT Application No. PCT/US2017/061388, filed Nov. 13, 2017; which claims the benefit of U.S. Provisional Application Nos. 62/564,574, filed Sep. 28, 2017, and 62/422,535, filed Nov. 15, 2016; which applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Impressions are used in the hearing aid industry to provide models of the hearing aid user's ear canal. These impressions taken of the lateral end of the ear canal may be used to create ear tips (the portion of the hearing aid that fits into the lateral end of the ear canal) which conform to the actual shape of the user's ear canal. These custom ear tips generally provide better fit and comfort than ear tips which are not custom fitted to the customer's particular ear canal shape. In contact hearing aid systems which include hearing aid components (e.g., contact hearing devices) which are positioned on and conform to the shape of the user's tympanic membrane (ear drum), impressions may be taken that extend from the lateral end of the ear canal (e.g., near the pinna) to the medial end of the canal (e.g., at or near the tympanic membrane). These full canal impressions may be used to manufacture both custom ear tips and custom contact hearing aid components, such as contact hearing devices, for the user's tympanic membrane. The methods of taking these full canal impressions, along with the characteristics of the materials used to take the impressions will have an impact on the overall fit, comfort and utility of the components manufactured using that full impression. As used herein, ear tip may refer to a conventional hearing aid ear tip (e.g., including a receiver) or to a light tip which may be a component of a contact hearing system.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of embodiments of the present inventive concepts will be apparent from the more particular description of preferred embodiments, as illustrated in the accompanying drawings in which like reference characters refer to the same or like elements. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the preferred embodiments.

FIG. **1** illustrates an impression being taken with the subject in a supine position and a health care professional injecting the impression material into the subject's ear canal.

FIG. **2** illustrates an impression being taken with the subject in an upright position and a health care professional injecting the impression material into the subject's ear canal.

FIG. **3** illustrates a scanned image of the medial end of a lateral ear canal impression.

FIG. **4** illustrates a scanned image of a lateral ear canal impression with a portion of the medial end removed.

FIG. **5** illustrates a scanned image of a lateral ear canal impression overlaid over a scanned image of a full canal impression.

FIG. **6** illustrates a digital model of a lateral impression including an overlapping region.

FIG. **7** illustrates a digital model of a combined medial and lateral impression, including an overlapping region.

FIG. **8** illustrates a digital model of a combined medial and lateral impression, including a junction.

FIG. **9** illustrates a digital model of a combined medial and lateral impression after the junction has been smoothed.

FIG. **10** illustrates an impression kit according to one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** illustrates an impression being taken with the subject in a supine position and a health care professional **190** injecting the impression material into the subject's ear canal. In one embodiment of the invention, two different impressions are taken and digitally scanned. In this embodiment, the different impressions represent two different (although overlapping) portions of the ear canal anatomy and are made using two different viscosities of impression material. In this embodiment, the first impression (Impression **1**) may be either: a) an impression of the whole ear canal, down to and including the tympanic membrane or b) an impression of the medial portion of the ear canal from approximately the beginning of the bony canal to and including the tympanic membrane. The Impression **1** impressions may be made using a low viscosity impression material with the subject lying in a supine position (the supine position is chosen to prevent the low viscosity impression material from running out of the subject's ear before it cures). The use of a low viscosity material for Impression **1** enables the impression to reflect the fine detail of the anatomy of the medial ear canal since it flows easily into all areas of the medial ear canal.

FIG. **2** illustrates an impression being taken with the subject in an upright position and a health care professional **190** injecting the impression material into the subject's ear canal. In embodiments of the invention, the second impression (Impression **2**) is an impression of the lateral portion of the ear canal wherein the impression extends from a point in the subject's bony canal (but not as deep as the tympanic membrane) to the subject's concha bowl. Impression **2** is made using a high viscosity material with the subject in an upright (sitting) position to obtain an impression of the lateral ear canal which is most representative of the shape of the ear canal when the subject is in the position where he/she is most likely to be when using the hearing aids (e.g., sitting or standing). As the impression material cures, the high viscosity material exerts pressure on the tissue in the lateral ear canal, causing slight compression of the tissue in the lateral ear canal, thus creating an ear tip which fits snugly into the lateral ear canal and will not migrate out of the ear canal. The pressure is created by the viscosity of the high viscosity impression material and the force it exerts on the ear canal.

In one embodiment of the invention, once the impressions are made they may be shipped back to the manufacturer where they are cleaned and placed into a digital scanner. The digital scanner is used to make digital models of the impressions, which digital models may be representative of all or sections of the subject's ear canal. Where Impression **1** is an impression of the whole ear canal, down to and including the tympanic membrane, the output of the scanner for Impression **1** is a digital model of the full ear canal which includes a medial portion representative of the shape, size and surface structure of the entire ear canal, including the medial portion, tympanic membrane and sulcus region. Where Impression **1** is an impression of the medial end of the ear canal, down to and including the tympanic membrane, the output of the scanner for Impression **1** is a digital model of the medial end of the ear canal representative of the shape, size and surface structure of the tympanic membrane and sulcus region. The output of the scanner for Impression **2** is a digital model which includes a first portion representative of the shape, size and surface structure of the lateral end of the ear canal and may also include a second portion representing a medial end of Impression **2**.

Once Impression **1** and Impression **2** are complete, and have been scanned using, for example, a digital scanner, digital representations of Impression **1** and Impression **2** are created. The resulting scans are combined by the technique described below to create a single digital representation of the ear canal of the subject, including digital features representative of the surface of the subject's ear canal. The resulting digital representation will represent the subject's ear canal from the concha bowl to the tympanic membrane. This single digital representation combines the representation resulting from the use of a high viscosity impression material to create a model of the lateral ear canal (higher pressure conforms to soft tissue of lateral ear canal) and the representation resulting from the use of a low viscosity impression material to create a model of the medial portion of the ear canal (lower viscosity allows it to flow evenly into the farthest reaches of the ear canal without creating bubbles or missing areas which might ruin the impression and make it difficult to create a resulting product). The low viscosity impression material further allows the impression to capture the fine detail of the tympanic membrane and sulcus region.

As illustrated in FIGS. **3** and **4**, once the scans are completed, the digital model (scan) of Impression **2** may be "cleaned up" (i.e., digitally altered) to, for example, remove data which is not representative of the anatomy of the subject. This extraneous data may result from impression material at the medial end of the impression which did not contact any portion of the ear canal. In the digital model, this additional data, which is not representative of the actual shape of the subject's ear canal be referred to as noise. See, for example, the portion of digital model **20** labeled **10** in FIG. **3**, this portion of digital model **20** has been removed in FIG. **4**.

Once the extraneous data is removed from digital model **2**, the corresponding portions of the data files for models **1** and **2** may be overlaid to obtain a best fit alignment for the overall impressions. This best fit analysis may be performed either manually or electronically. In either case, the two models are overlaid and the features are used to get a best fit alignment. See, for example, FIG. **5** where digital model **20** of the medial end of the subject's ear canal is overlaid over digital model **30** of the entire ear canal of the subject. In FIG. **5**, the two digital models are manipulated until the corresponding alignment regions of digital model **20** and digital model **30** align as closely as possible. The required manipulation may be done either manually or using alignment algorithms.

Once digital models **20** and **30** are in rough alignment, an alignment region **40** may be identified on digital model **20** as illustrated in FIG. **6**. The alignment region **40** generally extends from the medial end **50** of digital model **20** to a starting point **60** representative of a predefined portion of the bony canal of the subject, which may be, for example, the beginning of the bony canal. The starting point **60** for the alignment region **40** may, alternatively, be defined with respect to other features of the ear canal, such as, for example, being defined as medial to the second bend. In FIG. **6**, alignment region **40** extends from starting point **60** to medial end **50** of digital model **20**. The bony canal is selected as alignment region **40** because it is an area where the two digital scans overlap. In addition the bony canal is the region of the ear canal least subject to changes in shape resulting from body position and/or pressure from the impression material, particularly the high viscosity impression material resulting from the curing process. The bony canal region is, therefore, believed to be the region in which the two digital models are most likely to be identical and/or similar enough to enable the two digital scans to be aligned. Thus, the alignment region is likely to be substantially the same in digital model **20** and digital model **30**.

Once the alignment region **40** is defined in digital model **20**, the alignment region **40** may be locally aligned with the bony canal region **70** of digital model **30** as illustrated in FIG. **7**. In embodiments of the invention, the alignment region **40** may be on the order of approximately 3 millimeters. Once the alignment region **40** is fully aligned with bony canal region **70**, the portion of digital model **20** which is medial to medial end **50** of digital model **30** is deleted. In embodiments of the invention, a small additional portion of digital model **30** is also deleted, leaving a small gap **100** as illustrated in FIG. **8**. In FIG. **9**, gap **100** is filled and smoothed to create a complete digital model **80** which incorporates data from digital model **20** as representative of the lateral ear canal and which incorporates data from digital model **30** as representative of the medial ear canal. This combined digital model **80** impression may then be used to design components which reside in the ear canal, such components may include ear tips, light tips, contact hearing devices, tympanic lenses and/or other components of contact hearing systems.

In alternative embodiments of the invention, complete digital model **80** may be made from a hybrid impression wherein the low viscosity impression material is first poured into the subject's ear canal, followed by the high viscosity impression material to create a single impression capturing the ear canal of the subject from the tympanic membrane to the concha bowl.

In alternative embodiments of the invention, the low viscosity impression may be left to fully cure while the subject is supine before moving the subject to an upright position and adding the high viscosity impression material. In this embodiment the low viscosity impression material may be used as an oto-block that prevents the high viscosity impression material from contacting the tympanic membrane and/or the medial end of the subject's ear canal.

In embodiments of the invention, the high viscosity impression material is bonded to the low viscosity impression material prior to removing the hybrid impression from the subject's ear canal.

In embodiments of the invention, one method of taking a hybrid impression of the ear canal of a hearing aid subject involves generating an impression using two separate materials through a predetermined series of steps, including ensuring that elements of the method are performed at predetermined time intervals. In embodiments of the invention, the predetermined time intervals may be determined as a function of characteristics of the impression material being used. In embodiments of the invention, such characteristics may include, for example, the curing time of the impression material. In embodiments of the invention, such characteristics may include, for example, the viscosity of the impression material.

In embodiments of the invention, the method may include the step of raising the subject from a supine to a sitting (or standing) position at a predetermined time or after a predetermined event has occurred, for example within a predetermined interval after initially depositing impression material in the ear canal of the subject. Embodiments of the invention, which include the forgoing step, may be referred to as Seated Hybrid Impressions. In embodiments of the invention, the time interval may be calculated such that the subject is raised before the impression material used in the supine position is fully cured. In embodiments of the invention, the time interval may be calculated such that the subject is raised after the impression material used when the subject is in the supine position has cured to a point where it is sufficiently viscous that it does not flow out of the ear canal. In embodiments of the invention, the timing of raising the subject from a supine position into an upright position is dependent upon the timing of the transition of the impression material from a viscous material to a gel. In embodiments of the invention, a sol to gel transition, in which the material is transformed from what is technically a liquid (sol) into a solid (gel) is the preferred point for raising the subject from a supine to an upright position. In embodiments of the invention, it may be possible to raise the subject before the impression material transitions from a liquid to a solid. For example, the subject may be raised when the impression material's viscosity increases enough to prevent the impression material from flowing out of the ear when the subject is raised to the upright position.

In embodiments of the invention, materials which are suitable for creating impressions of the medial end of the ear canal include materials which initially have a low viscosity, such as, for example, a viscosity of less than 10 centipoise ("cPs") and/or a viscosity of between approximately 10 cPs and 20,000 cPs. Impression materials suitable for use in low viscosity applications of the present invention may be referred to herein as Low Viscosity Impression Materials or LVIM. In embodiments of the invention, materials suitable for use as an LVIM may have a hardness of approximately 15±2 Shore A. In embodiments of the invention, materials suitable for use as an LVIM may have an Elongation at break of greater than approximately 250%. In embodiments of the invention, the viscosity values set forth above represent the viscosity of the impression material as it is initially deposited in the ear canal of the subject using, for example impression dispensing gun **110**. In embodiments of the invention, wherein the impression material is a two part material which is mixed prior to injecting it into the subject's ear canal, the viscosity values set forth above represent the viscosity of the impression material immediately following the mixing of the two materials which comprise the two part impression material.

In embodiments of the invention, materials which are suitable for creating impressions of the lateral end of the ear canal include materials which have a higher viscosity than the Low Viscosity Impression Materials, such as, for example, a viscosity of more than 100 cPs and/or a viscosity of between approximately 100 and 100,000 cPs. Impression materials suitable for use in high viscosity applications of the present invention may be referred to herein as High Viscosity Impression Materials or HVIM. In embodiments of the invention, materials suitable for use as an HVIM may have a hardness of approximately 30±3 Shore A. In embodiments of the invention, materials suitable for use as a HVIM may include Otoform A softX having a hardness of approximately 25+/−2 Shore A.

In embodiments of the invention, materials suitable for creating impressions may include two-part, platinum cure silicones. Once the two components of the impression materials are mixed together, these materials increase in viscosity over time and ultimately cure into a solid material. After a period of time, the material undergoes what is known as a sol-gel transition, in which the material is transformed from a liquid state (sol) to a soft, solid state (gel). The gel may continue to cross-link (or cure) over time so that it becomes harder than the gel, and eventually is fully cured. The fully cured material will not undergo any shape change when it is released from a physical constraint, such as when it is removed from an ear canal. Instead, the fully cured material retains the geometry it had when it transitioned from a gel to a fully cured solid.

In embodiments of the invention, factors which can affect the timing of moving a subject from a supine to an upright position while making an impression of the subject's ear canal include: i) the temperature of the impression materials (higher temperatures result in faster cures); ii) the ratio of the two components comprising the impression material (1:1, 2:1, or other ratios); iii) the initial concentration of platinum catalyst; and iv) the presence of any inhibitors of the platinum catalyst (such as alcohols, amine-containing chemicals, sulfur-containing chemicals or materials, and phosphorous-containing chemicals, among others). For example, certain HVIM materials cure faster than the LVIM materials, with the former reaching a gel state in about 1 minute, while the latter reaches a gel state in about 2 minutes at normal body temperature.

In embodiments of the invention, the method may use a serial procedure to gather a full seated Hybrid Impression from one ear before moving to the second ear. Alternatively, a health care professional may inject the LVIM materials into both ear canals of the subject before moving the subject from a supine to an upright position. In an embodiment of the invention, the health care professional may alternate between the right and left ears, for example, injecting LVIM in the left ear followed by HVIM in that ear, followed by LVIM in the right ear and then HVIM in the right ear. In embodiments of the invention, the patient may move from a sitting position to a supine position after injecting the first HVIM material but before it is fully cured.

In embodiments of the invention, the following steps may be used to create a Seated Hybrid Impression. The steps include:

1. The step of reclining the subject into a supine position, putting Low Viscosity Impression Materials into the subject's ear such that the LVIM extends into the medial end of the subject's ear canal. In embodiments of the invention, the physician will continue to put LVIM into the ear canal of the supine subject until the LVIM reaches a predetermined region of the subject's ear canal. In embodiments of the invention, the predetermined region may be the subject's Cartilaginous Boney Junction ("CBJ"). In embodiments of the invention, the predetermined region may be a point just beyond the subject's CBJ. In embodiments of the invention, the predetermined region may be the region designated as the lateral smooth glandular tissue area. In embodiments of the invention, the predetermined region may be the medial end of the second bend in the subject's ear canal. In embodiments of the invention, the physician may continue to put LVIM into the subject's ear canal until the LVIM material is far enough lateral to allow the injection tool for the HVIM to reach the lateral end of the LVIM material. In embodiments of the invention, the injection of LVIM must be completed within a first predetermined period of time. In embodiments of the invention, the first

predetermined period of time may be the time required for the LVIM to increase in viscosity such that it will no longer flow out of the subject's ear canal. In embodiments of the invention, the first predetermined period of time may be less than the time required for the LVIM to fully harden or cure. In embodiments of the invention, the first predetermined period of time may be approximately one minute and 15 seconds following the initial mixing of LVIM material for deposition in the subject's ear canal. In embodiments of the invention, the LVIM material is a 2 part material which only begins to cure after the two parts are mixed together. In embodiments of the invention where the deposition of LVIM takes less than the first predetermined period of time, the subject may be maintained in the supine position until the end of the first predetermined period of time. In embodiments of the invention, the subject may be raised to an upright position just after the LVIM transitions from a viscous liquid to a gel but before it fully cures. In embodiments of the invention, the subject may be raised into an upright position before the LVIM gel fully cures.

2. The step of moving the subject into an upright (e.g., sitting or standing) position and allowing the LVIM material to fully harden or cure. In embodiments of the invention, the subject may be moved into an upright position after the end of the first predetermined period of time. In embodiments of the invention, the subject must be fully upright by the end of a second predetermined period of time where in the second predetermined period of time may be measured from the initial mixing of the LVIM prior to dispensing in the subject's ear canal. In embodiments of the invention, the second predetermined period of time, as measured from the initial dispensing of the LVIM in the subject's ear may be from approximately one minute and thirty seconds to two minutes and thirty seconds.
3. The step of injecting HVIM into the subject's ear canal. In embodiments of the invention, once the subject is in an upright position, HVIM material may be injected into the ear canal, starting at the lateral end of the LVIM impression material and working out to the end of the ear canal. In the embodiments of the invention, HVIM material may extend into the concha bowl of the subject. In embodiments of the invention, the HVIM material may extend to the level of the subject's scapha. In embodiments of the invention, the HVIM material may extend far enough to cover the subject's tragus.
4. The step of curing the HVIM material. In embodiments of the invention, the HVIM material may then be allowed to cure.
    a. Once the LVIM material is fully cured, the next step of the method may be to leave the first impression in the subject's ear, and take an impression of the subject's other ear using the steps set forth above.
5. The step of removing the hybrid impression from the subject's ear. In embodiments of the invention, both the LVIM and HVIM material may then be allowed to cure before removing the fully cured hybrid impression from the subject's ear. In embodiments of the invention, the process of fully curing the LVIM and HVIM material may take approximately eight minutes from the time the initial LVIM material was injected into the subject's ear canal. In embodiments of the invention, the physician may wait for a period of more than approximately eight minutes from the initial injection of the LVIM material to remove the hybrid impression from the subject's ear.
    a. If they have not already done so, once the hybrid impression has been removed from the subject's first ear, the physician may use the steps outlined above to take an impression of the subject's second ear.

In embodiments of the invention, the procedure described herein may be augmented by applying a cap of HVIM material over the LVIM material prior to moving the subject into an upright position as described in Step **2** above. In embodiments of the invention, the cap of HVIM material may be less than the full HVIM impression. In embodiments of the invention, the cap of HVIM material may be small enough to leave room in the subject's ear canal for additional HVIM material once the subject has been raised to the upright position. In embodiments of the invention, the cap of HVIM material may be approximately 3 millimeters to 20 millimeters thick.

The following timeline is illustrative of the timing of various steps of the sitting hybrid impression process according to one embodiment of the present invention. Sample Impression Timeline:

Impression Method		Total Time (min:sec)						
Hybrid		13:15						
0:15	0:30	0:45	1:00	1:15	1:30	1:45	2:00	2:15
Capture LVIM, Ear 1 (75 Sec)					Sit (15 Sec)	Capture HVIM, Ear 1 (30 Sec)		
2:30	2:45	3:00	3:15	3:30	3:45	4:00	4:15	4:30
HVIM Cure, Ear 1 (150 Sec)								
4:45	5:00	5:15	5:30	5:45	6:00	6:15	6:30	6:45
Recline (15 Sec)	Capture LVIM, Ear 2 (75 Sec)					Sit (15 Sec)	Capture HVIM, Ear 2 (30 Sec)	
7:00	7:15	7:30	7:45	8:00	8:15	8:30	8:45	9:00

-continued

HVIM + LVIM Cure (6 min, 30 Sec)								
9:15	9:30	9:45	10:00	10:15	10:30	10:45	11:00	11:15
HVIM + LVIM Cure (6 min, 30 Sec)								
11:30	11:45	12:00	12:15	12:30	12:45	13:00		13:15
HVIM + LVIM Cure (6 min, 30 Sec)								

In embodiments of the invention, the method may include placing the subject in a supine position and injecting LVIM into the subject's ear using enough LVIM to reach a predetermined point in the subject's ear canal. The subject would then remain in the supine position for approximately one minute and fifteen seconds before being moved to an upright position (e.g., sitting or standing). Approximately one minute and forty-five seconds later, the health care professional would inject HVIM into the subject's ear canal, using enough HVIM material to fill the ear canal to at least a point where the HVIM would be visible at the ear canal opening. In embodiments of the invention, the HVIM may be used to fill the ear canal to the Concha Cymba. In embodiments of the invention, the HVIM may be used to fill the ear canal to the concha bowl. In embodiments of the invention, the hybrid impression (including both the LVIM and HVIM) would be pulled from the subject's ear canal once the combined impression has bonded and fully cured.

In embodiments of the invention the low viscosity impression material may be a material particularly suited to making medial impressions. The LVIM may be Formasil AB (available from Dreve, Unna, Germany). The LVIM may be a low viscosity, two-part platinum cure silicone. The LVIM may have a viscosity which is sufficiently low, prior to mixing (approximately 1 to 1000 cPs), to ensure that it flows easily into the sulcus region and covers the tympanic membrane when it is injected into the ear canal of a subject. The LVIM may be selected to set up quickly. The LVIM may be selected to have a sol-gel transition time at 37° C. of approximately 1 to 3 minutes. The LVIM may be selected such that it becomes fully cured within 5 minutes of being injected into the ear canal of a subject. The LVIM may be selected to be a soft material, with a durometer of approximately 15±2 Shore A and a tensile strength of greater than approximately 1 MPa. The LVIM may be selected to have an excellent elastic recovery, such as an elastic recovery which is greater than approximately 99%.

In embodiments of the invention, the high viscosity impression material may be particularly suited to making lateral impressions. The HVIM may be Otoform A softX (available from Dreve, Unna, Germany). The HVIM may have a relatively high viscosity. The HVIM may be a two-part platinum cure silicone. The HVIM may have a viscosity prior to mixing of approximately 1,000 to approximately 100,000 cPs. The HVIM may be selected to have a viscosity which limits its ability to flow all the way down to the sulcus region, making it suitable for use in the outer, more lateral, portion of the subject's ear canal. The HVIM may be selected to set up faster than the LVIM. The HVIM may have a sol-gel transition time at 37° C. of approximately 30 seconds to approximately 1 minute. The HVIM may be selected to fully cure within approximately 4 minutes. The HVIM may be selected to be less soft than the LVIM. The HVIM may be selected to have a durometer of approximately 25±2 Shore A after complete curing. The HVIM may be selected to have an elastic recovery of greater than approximately 99%.

In one embodiment, the present invention is directed to a method of creating a hearing system for a subject, the method including the steps of: taking a first impression of a first portion of an ear canal using an impression material having a first viscosity; taking a second impression of a second portion of the ear canal using an impression material having a second viscosity; digitally scanning the first impression to create a first digital model; digitally scanning the second impression to create a second digital model; merging the first digital model with the second digital model to create a merged model where the lateral portion of the merged model is comprised of at least a portion of the first digital model and the medial portion of the merged model is comprised of at least a portion of the second model; and, using the merged digital model to manufacture at least one of an ear tip and a contact hearing device. In further embodiments of the invention, the method may include the step of raising the subject from a supine position to an upright position prior to the step of taking a second impression. In further embodiments of the invention, the second impression may be taken after the first impression is removed from the subject's ear canal. In further embodiments of the invention, the first impression may be taken after the second impression is removed from the subject's ear canal. In further embodiments of the invention, the first impression is an impression of the subject's whole ear canal, including the tympanic membrane, bony canal and lateral end of the ear canal. In further embodiments of the invention, the first and second portions of the ear canal overlap. In further embodiments of the invention, the first viscosity is lower than the second viscosity.

In one embodiment, the present invention is directed to a method of creating a hearing system for a subject, the method including the steps of: creating a hybrid impression of a subject's ear canal, the method of creating a hybrid impression including the steps of: injecting a low viscosity impression material into a first portion of the ear canal, wherein the low viscosity impression material is injected with the subject in a supine position; and, injecting a high viscosity impression material into a second portion of the ear canal lateral to the first portion, wherein the high viscosity impression material is injected with the subject in an upright position; digitally scanning the hybrid impression to create a digital model of the subject's ear canal; and, using the digital model to manufacture at least one of ear tip and a contact hearing device. In further embodiments of the invention, the initial viscosity of the low viscosity impression material is lower than the initial viscosity of the high viscosity impression material. In further embodiments of the invention, the method further includes the step of raising the subject from a supine position to an upright position prior to injecting the high viscosity impression material. In further embodiments of the invention, the subject is raised from a supine to an upright position after the low viscosity impression material has transitioned from a liquid to a gel state. In further embodiments of the invention, the subject is raised from a supine to an upright position before the low viscosity impression material is fully cured. In further embodiments of the invention, the step of raising the subject from a supine position to an upright position occurs at a predetermined time after the beginning of the step of injecting a low viscosity impression material. In further embodiments of the invention, the step of raising the subject from a supine position to an upright position occurs before the low viscosity impression material cures into a gel state. In further embodiments of the invention, the step of raising the subject from a supine position to an upright position occurs after the viscosity of the low viscosity impression material has increased to a viscosity where the low viscosity impression material no longer flows when subjected to gravitational forces. In further embodiments of the invention, the first and second portions of the ear canal do not overlap. In further embodiments of the invention the low viscosity impression is bonded to the high viscosity impression.

In one embodiment, the present invention is directed to a method of creating components of a hearing system for a subject, the method including the steps of: digitally scanning a first impression to create a first digital model, wherein the first impression is an impression of a first portion of an ear canal taken using a low viscosity impression material having a first viscosity and wherein the first impression has been taken with the subject in a supine position; digitally scanning a second impression to create a second digital model, wherein the second impression is an impression of a second portion of an ear canal taken using a high viscosity impression material having a second viscosity, and wherein the second impression has been taken with the subject in an upright position; merging the first digital model with the second digital model to create a merged model where the medial portion of the merged model is comprised of the first digital model and the lateral portion of the merged model is comprised of the second model; using the merged digital model to manufacture at least one of an ear tip and a contact hearing device. In further embodiments of the invention, the first and second portions of the ear canal overlap. In further embodiments of the invention, the first and second digital models include digital models of the overlapping portions of the ear canal. In further embodiments of the invention, the merging step includes aligning the digital models of the overlapping portions of ear canal. In further embodiments of the invention, the merging step includes aligning points within the digital models of the overlapping portions of the ear canal. In further embodiments of the invention, the first impression is an impression of the subject's whole ear canal, including the tympanic membrane, bony canal and lateral end of the ear canal.

In one embodiment, the present invention is directed to a method of creating components of a hearing system for a subject, the method including the steps of: digitally scanning a hybrid impression to create a digital model, wherein the hybrid impression has been created using a method including the steps of: injecting a low viscosity impression material into a first portion of the ear canal, wherein the low viscosity impression material is injected with the subject in a supine position; and, injecting a high viscosity impression material into a second portion of the ear canal lateral to the first portion, wherein the high viscosity impression material is injected with the subject in an upright position; using the merged digital model to manufacture at least one of an ear tip and a contact hearing device. In further embodiments of the invention, the low viscosity impression material has an initial viscosity which is lower than the initial viscosity of the high viscosity material. In further embodiments of the invention, the low viscosity impression material is bonded to the high viscosity impression material to create the hybrid impression.

In one embodiment the present invention is directed to a kit including: a low viscosity material for use in making impressions of the medial end of a subject's ear canal; and, a high viscosity material for use in making impressions of the lateral end of a subject's ear canal, wherein the initial viscosity of the low viscosity material is lower than the initial viscosity of the high viscosity material; and, at least one dispenser adapted to dispense at least one of the low viscosity material or the high viscosity material.

In one embodiment, the present invention is directed to a kit including: at least one impression dispensing gun; at least one dispenser of low viscosity impression material; at least one low viscosity impression material dispensing tip; at least one dispenser of high viscosity impression material; and, at least one high viscosity impression material dispensing tip. In further embodiments of the invention, the kit further includes at least one dispenser of mineral oil. In further embodiments of the invention, the kit further includes at least one mineral oil basin. In further embodiments of the invention, the kit further includes at least one impression return box.

Embodiments of the invention may include a kit useful in practicing the methods of the present invention. As illustrated in FIG. **10**, in one embodiment, the kit may include one or more of the following components: impression dispensing guns **110**; mineral oil **120**; a mineral oil basin (hex dish) **130**; low viscosity impression material **140**; low viscosity impression material dispensing tip **150**; impression return box **160**; high viscosity impression material **170**; and, high viscosity impression material dispensing tip **180**.

Definitions

Audio Processor (BTE)—A system for receiving and processing audio signals. In embodiments of the invention, audio processors may include one or more microphones adapted to receive audio which reaches the subject's ear. In embodiments of the invention, the audio processor may include one or more components for processing the received sound. In embodiments of the invention, the audio processor may include digital signal processing electronics and software which are adapted to process the received sound. In embodiments of the invention, processing of the received sound may include amplification of the received sound.

Contact Hearing System—A system including a contact hearing device, an ear tip, and an audio processor. In embodiments of the invention, contact hearing systems may also include an external communication device. An example of such system is an EarLens hearing-aid device that transmits audio signal by laser to tympanic membrane transducer (TMT) which is placed on an ear drum.

Contact Hearing Device (Tympanic Contact Actuator (TCA)/Tympanic Lens)—a tiny actuator connected to a customized ring-shaped support platform that floats on the ear canal around the eardrum, and resides in the ear much like a contact lens resides on the surface of the eye, where the actuator directly vibrates the eardrum which causes energy to be transmitted through the middle and inner ears to stimulate the brain and produce the perception of sound. In embodiments of the invention, the contact hearing device may include a photodetector, a microactuator connected to the photodetector, and a support structure supporting the photodetector and microactuator.

Ear Tip (Light Tip)—A structure designed to be placed into and reside in the ear canal of a hearing aid user, where the structure is adapted to receive signals intended to be transmitted to the user's tympanic membrane or to a device positioned on or near the user's tympanic membrane (such as, for example, a Contact Hearing Device). In one embodiment of the invention, the signals may be transmitted by light, using, for example, a laser positioned in the light tip. In one embodiment of the invention, the signals may be transmitted using radio frequency, using, for example, an antenna connected to the Ear Tip. In one embodiment of the invention, the signal may be transmitted using inductive coupling, using, for example, a coil connected to the Ear Tip.

Light Driven Hearing Aid System—a Contact Hearing System wherein signals are transmitted from the ear tip to the contact hearing device using light. In a light driven hearing system, light (e.g., laser light) may be used to transmit information, power, or both information and power to the contact hearing device.

Light Tip—an ear tip adapted for use in a light driven hearing aid system. In embodiments of the invention, a light tip may include a laser.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

REFERENCE NUMBERS

Number	Element
10	Digital Model of end of Digital Model 20 (noise)
20	Digital Model of lateral end of subject's ear canal
30	Digital Model including medial end of subject's ear canal
40	Alignment Region
50	Medial End of Digital Model 2
60	Starting Point of Alignment Region 40
70	Bony Canal Region
80	Complete Digital Model
100	Gap
110	Impression Dispensing Gun
120	Mineral Oil
130	Mineral Oil Basin
140	Medial Low Viscosity Impression Material
150	Medial Low Viscosity Impression Material Dispensing Tip
160	Impression Return Box
170	Lateral High Viscosity Impression Material
180	Lateral High Viscosity Impression Material Dispensing Tip
190	Health Care Professional
200	Subject

The invention claimed is:

1. A method of creating a hearing system for a subject, the method comprising the steps of:

taking a first impression of a first portion of an ear canal using an impression material having a first viscosity;

taking a second impression of a second portion of the ear canal using an impression material having a second viscosity;

bonding the first impression to the second impression;

raising the subject from a supine position to an upright position prior to the step of taking a second impression;

digitally scanning the first impression to create a first digital model;

digitally scanning the second impression to create a second digital model;

merging the first digital model with the second digital model to create a merged model where the lateral portion of the merged model is comprised of at least a portion of the first digital model and the medial portion of the merged model is comprised of at least a portion of the second model; and

using the merged digital model to manufacture at least one of an ear tip and a contact hearing device.

2. A method according to claim 1, wherein the first impression comprises an impression of the subject's tympanic membrane.

3. A method according to claim 1, wherein the first and second portions of the ear canal overlap.

4. A method according to claim 1, wherein the first viscosity is lower than the second viscosity.

5. A method of creating a hearing system for a subject, the method comprising the steps of:

creating a hybrid impression of a subject's ear canal, the method of creating a hybrid impression comprising the steps of:

injecting a low viscosity impression material into a first portion of the ear canal, wherein the low viscosity impression material is injected with the subject in a supine position; and

injecting a high viscosity impression material into a second portion of the ear canal lateral to the first portion, wherein the high viscosity impression material is injected with the subject in an upright position;

bonding the high viscosity impression material to the low viscosity impression material;

digitally scanning the hybrid impression to create a digital model of the subject's ear canal; and

using the digital model to manufacture at least one of ear tip and a contact hearing device.

6. A method according to claim 5, wherein the viscosity of the low viscosity impression material is lower than the viscosity of the high viscosity impression material.

7. A method according to claim 5, further including the step of raising the subject from a supine position to an upright position prior to injecting the high viscosity impression material.

8. A method according to claim 7, wherein the subject is raised from a supine to an upright position after the low viscosity impression material has transitioned from a liquid to a gel state.

9. A method according to claim 8, wherein the subject is raised from a supine to an upright position before the low viscosity impression material is fully cured.

10. A method according to claim 6, wherein the step of raising the subject from a supine position to an upright position occurs at a predetermined time after the beginning of the step of injecting a low viscosity impression material.

11. A method according to claim **6**, wherein the step of raising the subject from a supine position to an upright position occurs before the low viscosity impression material cures into a gel state.

12. A method according to claim **8**, wherein the step of raising the subject from a supine position to an upright position occurs after the viscosity of the low viscosity impression material has increased to a viscosity where the low viscosity impression material no longer flows when subjected to gravitational forces.

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